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SURFACE AND 60 FSW PERFORMANCE TESTING OF THE MODIFIED MBS 2000 CLOSED CIRCUIT OXYGEN REBREATHER

by

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14. ABSTRACT

This report describes the operation and performance characteristics of a closed circuit oxygen rebreather that is designed to provide oxygen for on-scene decompression of submarine survivors in the Submarine Rescue Diving and Recompression System (SRDRS) and recompression treatment of divers aboard submarines. The data contained in this report provides engineers and medical support personnel with an estimate of the amount of oxygen needed to support recompression treatment of DISSUB survivors in the SRDRS. The report also provides information on operational medicine issues associated with the trade off between oxygen usage and the oxygen dosage needed to support a recompression treatment using the MBS 2000.

15. SUBJECT TERMS

oxygen, rebreathing, closed-circuit rebreather, oxygen recompression treatment, purge procedures, hyperbaric oxygen treatment

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NAVSEA 00CM

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ADMINISTRATIVE INFORMATION

The views expressed in this report are those of the author and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the United States Government. The study protocol NSMRL.2005.0001 was approved by the Naval Submarine Medical Research Laboratory Institutional Review Board in compliance with all applicable Federal regulations governing the protection of human subjects.

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Executive Summary

INTRODUCTION

The Morgan Breathing System (MBS) 2000 is a closed-circuit oxygen rebreather designed to provide oxygen for on-scene decompression of submarine survivors in the Submarine Rescue Diving and Recompression System (SRDRS) and recompression treatment of divers aboard submarines. There are concerns in each of these applications about having enough oxygen to support remote operations and having sufficient ventilation capacity to prevent excess O_2 leaking into the compartment. Therefore, in FY05 NSMRL conducted initial manned testing of the MBS 2000 with the objective of developing efficient purge procedures and defining oxygen consumption rates for clean shaven and unshaven subjects at 1 ATA. Lessons learned from the FY05 testing pointed to several potential design modifications that could be made to the MBS 2000 unit to improve purge efficiency and reduce oxygen usage rates. This report describes the modifications that were made to the MBS 2000 and the subsequent manned performance of the modified unit at 1 ATA and 60 fsw.

OBJECTIVES

The primary objective of the current study was to use the lessons learned from the FY05 testing to improve the design and efficiency of the current MBS 2000 unit. Specific design modifications chosen for testing were aimed at improving purge efficiency and reducing the oxygen volume requirements needed to accommodate purges and any leaks of ambient air into the system during a treatment. Since all previous testing had been performed at 1 ATA, a second major objective for the FY06 tests was to evaluate the modified MBS 2000 rebreather at 60 fsw in a hyperbaric chamber. In particular, data on purge frequency and oxygen consumption at depth was sought to provide more accurate calculations of the total volume of oxygen needed to support an operation.

METHODS

The design modifications made to the MBS 2000 that underwent human performance testing are given below.

1. Incorporation of a two-way slide valve on the exhaled side of the MBS 2000 main body.
2. Elimination of the overpressure relief valve on the main body.
3. Incorporation of four hose clamps/breathing hose retainers for maintenance of a gas tight seal between the breathing hoses and main body and valve assembly.
4. Replacement of the old rubber facemask with a silicone face mask and head net made by SEA-LONG (Series 700, SEA-LONG Medical Systems Inc., Louisville, KT).
5. Incorporation of a removable T-bit mouthpiece in the breathing valve T-assembly.
6. Incorporation of the R10-DN oxygen sensor into the end cap of the inhalation side of the MBS 2000 valve main body.
7. Removal of the flow restrictor in the pressure oxygen supply whip.

Human performance testing of the modified MBS 2000 was conducted in two phases. In phase I, 7 submariners (mean ± SD age = 23.6± 7.9 yrs, forced vital capacity (FVC) = 5.4 ± 0.9 L BTPS) and 8 divers (age =36.67 ± 12.2 yrs, FVC 5.6 ± 0.7 L BTPS) each performed two 70 minute O_2 rebreathing trials with the modified MBS 2000 unit at 1 ATA. During one trial subjects breathed from the unit using the SEALONG oral nasal mask (SL-Mask condition) while in the other trial T-bit mouthpiece was inserted into the breathing valve in an attempt to reduce mask leaks (T-bit condition). In phase II, 11 U.S. Navy trained divers (mean ± SD age =37.0 ± 10.8 yrs, FVC 5.5 ± 0.7 L BTPS) conducted a dry hyperbaric chamber dive to 60 fsw. The dive profile involved 60 minutes breathing chamber air at 60 fsw followed by two 20-minute oxygen breathing periods using the modified MBS 2000 (with SEALONG oral nasal mask plus T-bit). During each trial the subjects FiO_2 was monitored continuously using an R10-DN oxygen cell and compared with gas sample measurements taken using an MGA mass spectrometer or S-3A oxygen analyzer. Measuring changes in O_2 supply bottle pressure allowed continuous measurement of the volume of oxygen used by each subject.

The initial purge procedure involved the subject conducting 10 medium to large open circuit breaths with the slide valve in the open circuit position. After exhaling the 10th breath, the subject moved the slide valve to the closed circuit position, inhaled a large breath and began closed-circuit breathing. Any additional purges after the initial purge were performed in the same manner as that described above except that 5 large open circuit breaths instead of 10 breaths were conducted prior to beginning closed-circuit breathing. Additional purges during the 1 ATA trials were conducted only if their FiO_2 dropped below 0.70 and after the five-minute air break at 65 min. During the 60 fsw trials additional purges were performed only if their FiO_2 dropped below 0.80 and after the five minute air break following the first 20 min O_2 period.

RESULTS

Phase I Tests

The mean ± SD purge volume for the 10 breath purge was 18.8 ± 6.8 l and 19.9 ± 7.4 l for the SL-Mask and T-Bit conditions respectively. This purge volume was significantly lower than the 28.3 ± 2.1 liters used in FY05 for purging the original MBS 2000 ($p<0.001$). The mean number of additional purges conducted over the 60 min O_2 breathing period were similar among the two mask conditions with the modified MBS 2000 and original MBS 2000 configuration. However, the total volume of oxygen used during the 60 min O_2 period was significantly reduced from an average of 81.9 ± 30.7 l with the original MBS 2000 to 58.1 ± 19.6 l and 59.2 ± 27.0 l for the modified MBS 2000 with the SL-Mask and T-bit respectively ($p<0.05$). Furthermore, the modified MBS 2000 significantly extended the mean time that the dry FiO_2 remained above 0.85 from 4 minutes with the original MBS 2000 to approximately 20 minutes with modified MBS 2000 ($p<0.001$).

Phase II Tests

At 60 fsw the average ± SD amount of oxygen used during the first 20 min O_2 period was significantly greater than that used during the second 20 min O_2 period (110.2 ± 39.6 l vs 95.6 ± 2.4 l, $p<0.001$). The difference in oxygen usage between the two O_2 periods reflects the larger volume of O_2 used for the 10 breath purge during the initial purge for the first O_2 period compared with the 5 breath purge used at the start of the second O_2 period (mean 10 breath purge volume = 81.5 ± 17.9 l vs mean 5 breath purge volume = 44.8 ± 9.7 l, $p<0.001$). When the initial purge volume is subtracted from the total oxygen usage there was no significant difference in the volume of oxygen used between the first and second 20-minute O_2 periods. The mean initial starting dry FiO_2 was significantly higher following the 10 breath purge (97.8 ± 1.2%) than for the 5 breath purge (95.6 ± 2.4 %, $p<0.01$). However, the mean dry FiO_2 averaged over the entire 20 minutes was similar between the first O_2 period (93.4 ± 2.1%) and second O_2 period (92.5 ± 2.8%, $p>0.05$).

CONCLUSIONS

The modifications made to the MBS 2000 significantly improved performance of the MBS 2000 unit with respect to both reducing oxygen usage and maintaining a high FiO_2 for a longer period of time. In particular, the inclusion of the purge slide valve allowed for a simpler and more efficient purge procedure. Purging the modified MBS 2000 with the 10-breath and 5-breath open circuit method reduced the purge volume by approximately 30% and 60%, respectively, compared to the volume of O_2 used with the optimum purge procedure developed in FY05 for the original MBS 2000. Although the modified MBS 2000 did not reduce the number of purges required during the surface trials, the 5 breath purge procedure reduced the mean volume of oxygen used over 60 min by approximately 30% compared with that used during the FY05 trials with the original MBS 2000.

The validation trails at 60 fsw showed that both the 10 and 5 breath purge procedures raised the starting dry FiO_2 to >95% and that most subjects could maintain their mean dry FiO_2 above 90% over 20 minutes. When the mean O_2 volume used during the 60 fsw trails is converted to an equivalent surface pressure volume (i.e. divided by 2.82 ATA) and presented as the rate of O_2 use/man, the first 20 minute O_2 period used approximately 2.0 liters/min/man and the second O_2 period used 1.1 liters/min/man. The higher oxygen usage during the first period reflects the higher O_2 volume used for the initial 10-breath purge procedure. It should be noted that the above O_2 use/man is a mean value and that there can be considerable variation in oxygen usage between individuals depending on their ability to maintain a good mask seal. Although inclusion of the T-bit insert into the mouthpiece did not significantly improve performance over that obtained with the oral nasal mask only, further design modification of the T-bit insert may improve mask fit and reduce mask leaks.

Introduction

This report provides the results of performance testing of the Morgan Breathing System 2000 closed circuit oxygen rebreather (MBS 2000) that was modified from its previous configuration, as originally tested and reported in Fothergill (2005a). Additional detail on previous testing and development of the MBS 2000 can be found in the NSMRL technical reports written by White et al., (2000) and Fothergill (2005a).

During December of 2004 NSMRL conducted manned purge testing of the MBS 2000 on 9 submariners and 9 divers with the goal of developing a purge procedure that would raise the inspired level of oxygen within the closed circuit of the MBS 2000 to >95% with significantly less oxygen than the currently recommended purge procedure (Fothergill, 2005a). Of the five different purge procedures tested the simplest and most preferred purge procedure was the CR15. This purge procedure involved the subject exhaling to residual volume then donning the MBS 2000 mask and conducting a 15 sec purge by pressing the MBS 2000 regulator purge valve. During the 15 s purge the subject performed 3 deep breaths allowing the exhaled portion of the breath to escape around the sides of the oral nasal mask. After the 15 s purge the subject released the regulator cover and breathed normally for 30 s. The above 15 s purge procedure was repeated one more time before commencing normal breathing on the unit.

When compared with the purge procedure recommended by the manufacturer (CR) the CR15 purge procedure achieved a similar starting FiO_2, but with approximately two thirds less oxygen. The volume of O_2 used during the CR15 purge was also compared with a purge procedure involving multiple vital capacity (MVC) breaths. When a mathematical model was fit to the group mean data for the FiO_2 plotted as a function of the number of vital capacity breaths it was found that between 6 and 7 vital capacity breaths were required for the FiO_2 within the MBS 2000 closed circuit to exceed 0.90 (Fothergill, 2005a). This required between 20 - 24 l of oxygen at 1 ATA a value that was not too dissimilar from the 28 l of O_2 required for the CR15 purge.

From January to March 2005 oxygen consumption and mask leak rates for the MBS 2000 were determined in the same subject population (Fothergill 2005a). The objectives of this second phase were to:

(1) Determine the average number of purges required to maintain the oxygen level in the breathing loop above 70%, above 80%, and above 90% during a 60 min breathing period following an initial purge at 0 fsw.

(2) Determine mask leak rates in shaved and unshaven subjects at 1 ATA.

(3) During the purge procedures and while breathing on the MBS 2000 closed circuit at 1 ATA determine the rate of build up of oxygen in the enclosed atmosphere of the chamber over a 60 min period.

Group mean results for the leak rates determined in clean shaven subjects are shown in Figure 1. The data in Figure 1 show that the FiO_2 within the closed-circuit quickly drops below 0.90 and within 10 minutes of closed-circuit breathing approaches 0.80. There was however large variability between individuals in the rate at which the oxygen concentration in the closed circuit fell. This likely reflected differences in mask fit between individuals, which contribute to potential air leaks into the MBS 2000. If the mean time taken for the FiO_2 within the MBS 2000 unit to fall to 0.80 can be considered a reasonable compromise between purge frequency and oxygen dosage for a decompression treatment, then based upon the group data for the clean-shaven trials shown in Figure 1 a purge should be performed every 10 min during the initial O_2 breathing period. A second finding from the phase II trails was that heavy beard growth increases the amount of chamber air leaking around the sides of the MBS 2000 oral nasal mask into the breathing circuit leading to an increased purge frequency to maintain the F_IO_2 above a given level (Fothergill 2005b). Further details of the results from the FY05 testing are given in Fothergill (2005a)

During operational use of the MBS 2000, it became clear that the overpressure relief toggle valve used during the purge procedure was problematic due to the small orifice causing a high back pressure leading to most of the exhaled breath escaping around the sides of the mask rather than through the expired breathing loop during the CR purge procedure. Furthermore, inappropriate use of this toggle valve during the purge procedure could lead to an ineffective purge that would quickly lead to the subject loosing consciousness as a result of the oxygen within the closed-circuit reaching hypoxic levels once closed-circuit breathing had commenced. To avoid the potential for this latter scenario the overpressure relief toggle valve was replaced with a newly designed pop-off valve. Preliminary human testing of this pop-off valve unfortunately showed similar problems with backpressure as that seen with the overpressure relief toggle valve.

Lessons learned from the FY05 testing pointed to several potential design modifications that could be made to the MBS 2000 unit to improve purge efficiency and reduced leak rates. Firstly, pilot experiments in FY05 suggested that a more efficient purge procedure could be achieved if the overpressure relief valve was replaced with a two-way Y-valve located on the main body on the expired side of the circuit (Fothergill 2005a). This modification would permit the entire unit to be purged in an open circuit mode without the backpressure problems associated with the overpressure relief toggle valve. Secondly, alternative mask designs and/or a T-bit mouthpiece may offer a better seal with the subject's mouth and face and thus reduce the potential for ambient air leaking into the closed-circuit breathing loop.

The primary objective of the current study was to use the lessons learned from the FY05 testing to improve the design and efficiency of the current MBS 2000 unit. Specific design modifications chosen for testing were aimed at improving purge efficiency and reducing the oxygen volume requirements needed to accommodate purges and any leaks of ambient air into the system during a treatment. To facilitate direct comparison with the FY05 tests, FY06 testing of the modified MBS 2000 incorporated the same basic 60-minute oxygen exposure at 1 ATA as was conducted for the FY05 tests (Fothergill 2005a).

Since all previous testing had been performed at 1 ATA, a second major objective for the FY06 tests was to evaluate the modified MBS 2000 rebreather at 60 fsw in a hyperbaric chamber. In particular, data on purge frequency and oxygen consumption at depth was sought to provide more accurate calculations of the total volume of oxygen needed to support an operation.

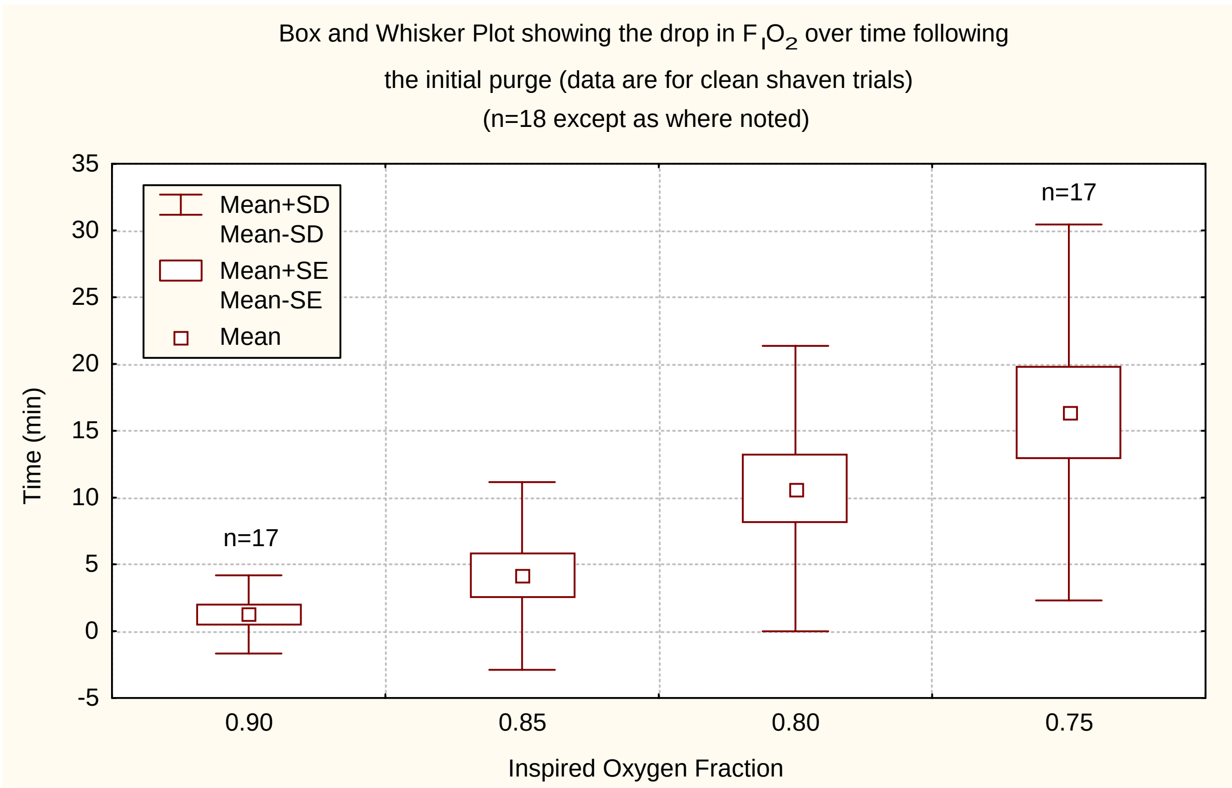

Figure 1: A box and whisker plot showing the average time taken for the concentration of oxygen within the original MBS 2000 closed circuit breathing loop to drop to various FiO_2 levels following the initial purge. Data are based on n=18 except as where noted. From Fothergill (2005a).

Phase I: Surface Testing of the modified MBS 2000

Methods

Subjects

Subjects were 7 submariners (mean ± SD age = 23.6± 7.9 yrs, forced vital capacity (FVC) = 5.4 ± 0.9 L BTPS) and 8 divers (age =36.67 ± 12.2 yrs, FVC 5.6 ± 0.7 L BTPS). Most of the submariners were recruited from the Basic Enlisted Submarine School at the Submarine Base, New London, CT and were significantly younger than the diver group ($p<0.05$). The diver group consisted of US Navy trained divers from NSMRL. Five of the divers and one of the submariner subjects had participated in the FY05 MBS 2000 tests. Despite differences in the mean age of the two groups there was no significant difference in the mean FVC between the diver and submariner group. Subjects were briefed on the studies objective and provided informed consent.

Apparatus

A total of three modified MBS 2000 units were constructed for testing. A picture of the modified MBS 2000 is shown in Figure 2. The primary changes to the MBS 2000 from that described in the 2005 report (Fothergill 2005a) were:

1. Incorporation of a two-way slide valve on the exhaled side of the MBS 2000 main body (see Figure 3).
2. Elimination of the overpressure relief valve on the main body. (The overpressure relief valve port on the MBS 2000 main body was sealed using an insert plug containing a double o-ring seal (see Figure 3).
3. Incorporation of four hose clamps/breathing hose retainers for maintenance of a gas tight seal between the breathing hoses and main body and valve assembly (see Figure 4).
4. Replacement of the old rubber facemask with a silicone face mask and head net made by SEA-LONG (Series 700, SEA-LONG Medical Systems Inc., Louisville, KT) (see Figure 4).
5. Incorporation of a removable T-bit mouthpiece in the valve T-assembly (see Figure 4).
6. Incorporation of the R10-DN oxygen sensor into the end cap of the inhalation side of the MBS 2000 valve main body.

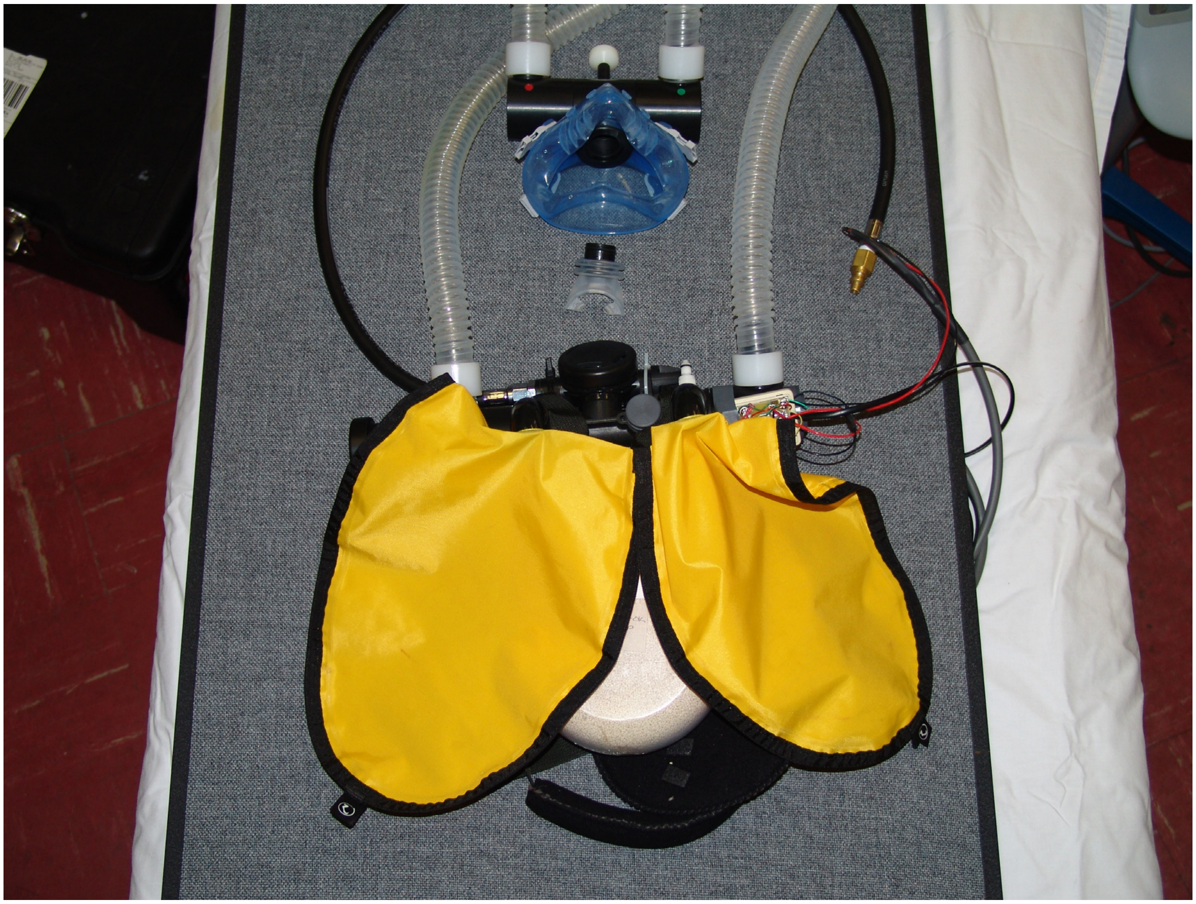

Figure 2: Photo of the modified MBS 2000 closed circuit oxygen rebreather. (See Figures 3 and 4 for more detail).

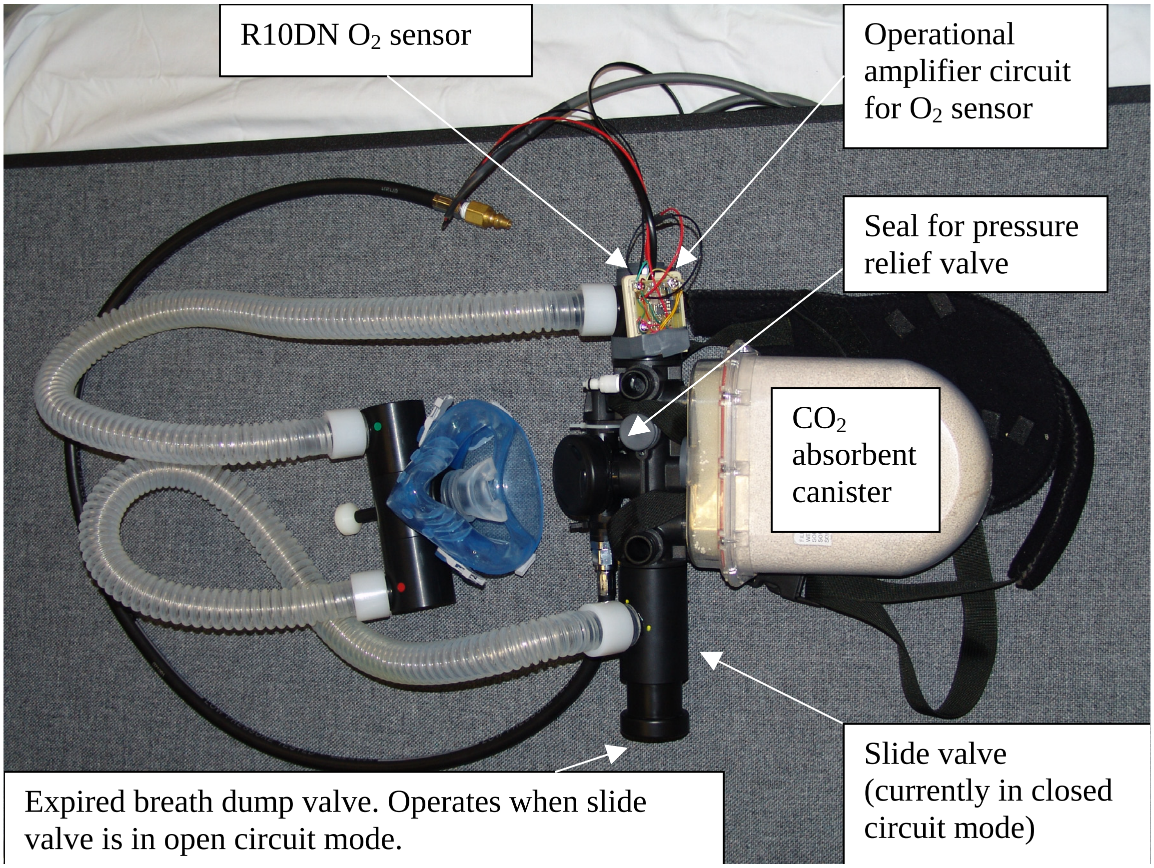

Figure 3: A photo of the modified MBS 2000 without the breathing bags showing the new slide valve attached to the main body on the expired side of the circuit. When the slide valve is placed in the open circuit position (slide valve pushed out to the full lateral position [i.e. downwards toward the expired end cap in the above picture]) expired breath is directed out of the closed circuit through a one way valve in the end cap of the slide valve. The R10-DN O_2 sensor together with its prototype operational amplifier is shown on the inspired side of the MBS 2000 main body.

Each subject was provided with a leak-tested MBS 2000 closed-circuit oxygen rebreather fitted with a CO_2 absorbent canister filled with 812 NI D grade Sofnolime™ (see Figure 2). Individual oxygen cylinders (255 l capacity M9 oxygen cylinders) supplied 100% medical grade oxygen to each MBS 2000 unit. Each oxygen cylinder was instrumented with a DP15-64 pressure transducer (Validyne Engineering, Northridge, CA) to monitor changes in bottle pressure. Output from the DP15-64 pressure transducers were amplified using CD 18 carrier demodulators before being sampled by a BIOPAC analogue to digital (A/D) recording system. The volume of oxygen used (in liters at 1 ATA and 25 °C) over a given time period was calculated from changes in bottle pressure. The second stage over bottom pressure for the regulator was set at 70 psi for all tests.

Oxygen levels within the MBS 2000 closed circuit were monitored continuously using a R10-DN oxygen sensor (Teledyne Analytical Instruments, Industry, CA) inserted into the end cap on the inspired side of the main body assembly. During the surface trials the operational amplifier for the R10-DN shown in Figure 3 was unavailable for testing. Thus output from the O_2 sensor was amplified using a Gould DC amplifier before being passed to the BIOPAC A/D recording system. The R10-DN oxygen cell was calibrated by disassembling the end cap and O_2 cell from the main valve body and then performing a two-point calibration. The first calibration was with room air (21% O_2) and the second was with 100% O_2. For the second calibration 100% medical grade O_2 was passed over the cell while monitoring the concentration at the cell surface at the same time with the mass spectrometer to confirm that the cell was exposed to 100% O_2. A linear fit between these two calibration points was assumed for the purpose of calibrating the cell voltage output.

During the surface trials at approximately 5 to 10 minute intervals a gas sample was drawn for at least 30 s from the sample port of each subjects MBS 2000 unit at a flow rate of 60 ml/min and passed through an MGA 1100 mass spectrometer for measurement of the dry gas faction for FiO_2, $FiCO_2$ and FiN_2. These periodic gas samples permitted the FiO_2 readings from the oxygen sensor to be corrected for water vapor pressure and errors due to fluctuations in gas temperature within the breathing circuit. As the volume of gas withdrawn from the closed circuit due to the periodic gas sampling was small it was ignored from the oxygen volume usage calculations.

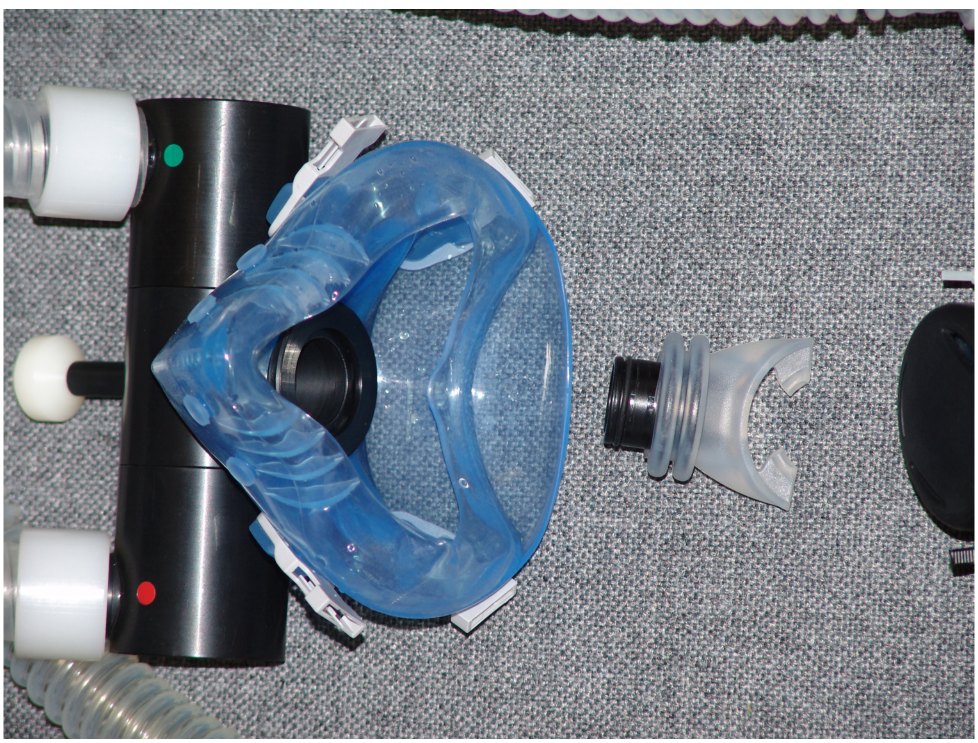

Figure 4: Close up of the SEA-LONG oral nasal mask and insert T-bit mouthpiece. The new hose clamps are also shown connecting the breathing hoses to the inspired (green dot) and expired (red dot) ports of the “T” valve.

Procedure

All experiments were performed with subjects seated at rest at surface pressure (see Figure 5). Trials consisted of a single 60-min O_2-breathing period followed by a 5 min air break and then a further 10 min O_2 breathing period. Each subject conducted two trials on separate days. During one trial subjects wore the SEA-LONG oral nasal mask without the T-bit insert (SL-MASK), while in the other trial they used the SEA-LONG oral nasal mask with the T-bit insert (T-BIT). For this latter condition the oral nasal mask provided a seal over the face while the head net assembly helped support the T-bit in the mouth. Nose clips or other devices to prevent nasal breathing were not employed during the T-BIT trials. The order of the SL-MASK and T-BIT trials was counterbalanced among the subject group.

Figure 5: Three subjects undergoing a 60 min O_2 breathing period at surface using the modified MBS 2000 closed circuit oxygen rebreather. A gas sample line is currently attached to the gas sample port of the MBS 2000 unit of the middle subject.

Purge Procedure
The initial purge procedure involved the subject donning the mask/T-bit and then conducting 10 medium to large breaths with the slide valve in the open circuit position. After exhaling the 10^{th} breath, the subject moved the slide valve to the closed circuit position, inhaled a large breath and began closed-circuit breathing. Any additional purges after the initial purge was performed in the same manner as that described above except that 5 large open circuit breaths instead of 10 breaths were conducted prior to beginning closed-circuit breathing. Additional purges during the 60 min O_2 breathing period were conducted only if their FiO_2 dropped below 0.70. The FiO_2 measurement used for initiating the purge was the dry inspired oxygen fraction, which was determined online by adjusting the R10-DN FiO_2 measurements using the previous mass spec FiO_2 sample. At the end of the 60-minute O_2 breathing period subjects inserted the slide valve piston on the valve "T" assembly, took off their mask, and breathed air for 5 min. After the 5 min air break subjects re-purged the MBS 2000 using the 5 breath open circuit procedure and completed a final 10 min O_2 breathing period.

Analysis
The volume of oxygen used at the end of the first 60 min rebreathing period was determined for each subject from the change in bottle pressure. Statistical analysis comparing the volume of oxygen used over the 60 min between the original mask (O-MASK) and the SL-MASK and T-BIT was conducted using a one-way ANOVA. The rate of decline in FiO_2 after the initial purge for each mask condition was determined for each subject by measuring the time taken for the FiO_2 to reach the following levels: 0.90 and 0.85. These values were compared with those obtained during the clean-shaven FY05 trials with the O-MASK using a two-way ANOVA. The time taken for FiO_2 levels to reach 0.80 and 0.75 were not analyzed due to a large number of subjects not reaching these levels with the modified MBS 2000. It should be noted that 2 subjects under the SL-MASK condition and 2 subjects with the T-BIT condition never let their FiO_2 drop below 0.85 throughout the entire 60 min O_2 breathing period. For the purpose of analysis these subjects were assigned 60 min for their time to reach a FiO_2 of 0.85.

As an increasing number of subjects never let their FiO_2 drop below 0.70 during the tests a separate ANOVA was performed on the data to assess the time to the first purge among the different mask conditions. It should be noted that 6 subjects during the SL-MASK trial, 4 subjects during the T-BIT trial and 3 subjects during the O-MASK trial never let their FiO_2 drop below 0.70. Again, for the purpose of analysis these subjects were assigned a value of 60 min for the time to their first purge. Post hoc analysis for all the parametric statistics was conducted using Tukey's HSD test. All volumes are presented at standard temperature and pressure (i.e. 1 ATA and 25 °C). Data are presented as means ± SD except as where noted. Significance was set at $p<0.05$ for all tests.

Results

Ambient Conditions
The mean ± SD for ambient pressure and laboratory temperature during the trials were 762 ± 4 mmHg and 25.9 ± 2.1 °C, respectively.

Individual Subject Data
Individual subject data for FiO_2 and oxygen consumption are summarized in Tables A1 and A2 in Appendix A together with the raw data presented in graphical form. The graphical data are annotated with notes and are useful for determining the pattern in the decline of FiO_2 with time for individual subjects (i.e. whether there was a slow decline or a precipitous drop in FiO_2 due to a leak).

Leaks from a poor O-ring seal on the CO_2 absorbent canister were usually evident from sudden negative spikes/drops in the continuous FiO_2 waveform during inspiration. An example of these temporary drops in FiO_2 can be seen in the graphs for subject 8 in Appendix A. When there is a poor seal around the O-ring seal on the CO_2 absorbent canister the FiO_2 will tend to drop precipitously by more than 5% during each inhalation, even when there is little negative pressure within the breathing circuit. Although a larger diameter O-ring was used in an attempt to reduce these leaks the O-ring seal is still a potential source of leaks for air into the breathing circuit. This is due to the limited number of holding screws and flexible collar holding the lid of the CO_2 canister to the canister bottom.

Often the brief drop in FiO_2 resulting from a poor CO_2 absorbent canister lid seal was only observed in the mass spectrometer data and not in the R10-DN data. The likely reason that the R10-DN does not show these negative FiO_2 spikes in the data is that the R10-DN response time is too slow to pick up the temporary inspiratory leaks. In contrast, the response time of the R10-DN is adequate enough to measure the temporary positive spike in FiO_2 that occurs when an influx of oxygen is added to the closed circuit through activation of the second stage regulator. This is shown by the positive spikes in FiO_2 shown in the figures in Appendix A.

Comparison of R10-DN and Mass Spectrometer FiO_2 readings
The figures in Appendix A also provide a useful comparison between the FiO_2 measured with the R10-DN and that measured periodically with the mass spectrometer. Since the mass spectrometer adjusts for water vapor to give a dry fraction for FiO_2 where as the R10-DN measures the wet gas fraction it is expected that the R10-DN values for FiO_2 will be lower than the mass spectrometer readings taken at the same time point. The individual figures in Appendix A show that at the beginning of most trials the FiO_2 was approximately 0.02 to 0.04 lower for the R10-DN readings compared to the with the first mass spectrometer FiO_2 reading. However, as time progressed, the difference between R10-DN and mass spectrometer FiO_2 readings became greater. This is best illustrated in the surface trial for subject 15 with the SEALONG oral nasal mask with T-bit in which R10-DN and mass spectrometer FiO_2 measurements were recorded continuously throughout the trial. During the first 30 minutes the R10-DN gave FiO_2 values that were

on average 0.035 lower than those of the mass spectrometer. From 30 to 60 minutes the R10-DN gave FiO_2 values that were on average 0.106 lower than the mass spectrometer. During the final 10 minutes following the purge at 65 min the difference between the R10-DN and mass spectrometer FiO_2 readings had increased to 0.171.

Fothergill (2005) reported that the gas temperature inside the breathing loop near the FiO_2 sensor reached on average 38.1 ºC at the end of the 70 minutes of O_2 breathing during the FY05 tests. Assuming that the gas is 100% saturated with water vapor then the partial pressure of water vapor at this temperature is 50 mmHg. This represents a water vapor fraction of 0.066 within the breathing loop. As most of the figures in Appendix A show that the difference between the dry and wet fraction is a greater than 0.066 during the last 30 minutes of the test, it appears that the R10-DN significantly underestimates the true wet fraction for the FiO_2 after prolonged O_2 rebreathing on the MBS 2000.

There are a couple of possible reasons for the underestimation of the FiO_2 wet fraction as measured in the current configuration using the R10-DN. Firstly, at the end of each test significant amounts of water vapor were seen to have condensed on the oxygen sensor. This condensation may have effected the diffusion of oxygen into the cell and resulted in a falsely low reading. Secondly, the gas temperature is known to impact the voltage output from the oxygen cell. Although the R10-DN voltage output is temperature compensated to correct for changes in gas temperature it is possible that when gas temperatures approach the manufactures operating temperature limit of 40 ºC the temperature compensation mechanism becomes inaccurate.

Comparison of performance between original MBS 2000 unit and the Modified MBS 2000 Unit

Table 1 compares data collected during FY05 testing of the original MBS 2000 unit (Fothergill 2005a) with the performance of the modified MBS 2000 unit under the SL-MASK and T-BIT conditions. Results of the analysis of variance showed that for the majority of performance variables the modified MBS 2000 outperformed the original MBS 2000. Purging the modified MBS 2000 with the 10-breath open circuit method reduced the purge volume by approximately 30% compared to the volume of O_2 used during the CR15 purge with the original MBS 2000. Although trials with the modified MBS 2000 did not reduce the mean number of purges required during the 60 min O_2 breathing period or the time to the first purge compared with the original MBS 2000 tests, the mean volume of oxygen used over the 60 min was reduced by approximately 30% with the modified MBS 2000. This latter finding reflects the use of the more efficient 5-breath purge procedure used to re-purge the modified unit when FiO_2 levels dropped below 70%. The 5-breath purge procedure results in almost a 60% decrease in oxygen usage when compared with the CR15 purge procedure used to re-purge the original MBS 2000 unit.

All the subjects easily performed both the 10-breath and 5-breath open circuit purge procedures. Eliminating the manually operated overpressure relief valve and adding the new slide valve reduced the risk of hypoxia resulting from incorrect purging of the unit and considerably simplified the purge procedure. It should be noted that the purge volumes for the SL-MASK and T-BIT conditions include the final breath volume used for closed circuit breathing. Estimates of the volume of oxygen released into the atmosphere from the purge procedures with the new MBS 2000 unit will thus be slightly less than the purge volumes given in Table 1. If we assume that the initial purge volume is comprised of 11 equal volume breaths and the reduced purge volume is comprised of 6 equal volume breaths then the average volume of oxygen released/man to the atmosphere during an initial and reduced volume purge will be approximately 18 and 10 liters, respectively. Note that due to the large tidal volumes used for the 5 breath purge procedure as well as the 6 large breaths vice 11 normal breaths used in the purge volume calculations for the 5 and 10 breath purge procedures, respectively, the 5 breath purge procedure commonly uses more than half the volume of oxygen of the 10 breath purge procedure.

Table 1: Comparison of the performance of the MBS 2000 among the three mask conditions for the surface 60-minute O_2 breathing trials. SL-MASK and T-BIT are for the modified MBS 2000 with the SEA-LONG oral nasal mask and the SEA-LONG oral nasal mask with t-bit mouthpiece insert, respectively. O-MASK data are from the FY05 evaluation of the MBS 2000 with the original rubber oral nasal mask. * red text = Significant main effect at $p<0.05$. NA = Not applicable

Variable	O-MASK (n=18)	SL-MASK (n=15)	T-BIT (n=15)	p
Mean Initial purge Volume (liters at 1 ATA and 25 °C)	28.3 ± 2.1 (n= 16)	18.8 ± 6.8	19.9 ± 7.4	<0.001*
Mean O_2 volume used over 60 min (liters at 1 ATA and 25 °C)	81.9 ± 30.7	58.1 ± 19.6	59.2 ± 27.0	0.019*
Mean Purge volume for reduced volume purge: 5 breath purge (liters at 1 ATA and 25 °C)	NA	12.2 ± 3.5	11.4 ± 3.3	0.309
Mean number of additional purges over 60 min (re-purge when $FiO_2 < 0.70$)	1.8 ± 1.5	2.1 ± 2.5	1.3 ± 1.7	0.428
Time after initial purge to reach FiO_2 of 0.90 (min)[1]	1.3 ± 2.9	12.3 ± 15.5	12.9 ± 11.4	<0.001*
Time after initial purge to reach FiO_2 of 0.85 (min)[1]	4.1 ± 7.0	19.0 ± 20.9	20.8 ± 20.6	<0.001*
Time to first purge i.e. 0.70 FiO_2 (min)[1]	27.7± 20.0	35.7 ± 24.8	38.2 ± 18.8	0.336

[1] FiO_2 limits are for corrected values (i.e. when the dry oxygen gas fraction reached 0.70, 0.85 or 0.90)

Comparison of Mask fit with the SEA-LONG oral nasal mask and SEA-LONG oral nasal mask with T-bit mouthpiece insert.

Statistical analysis comparing the SL-MASK and T-BIT conditions showed no significant difference in any of the variables analyzed. It thus appears that the SEA-LONG oral nasal mask alone provides just as good a seal to the face as the SEA-LONG oral nasal with T-

BIT mouthpiece. It should be noted however, that there were a number of subjects who had a poor mask seal because of either incompatible face anthropometry or because they chose the wrong size mask for the trials. Several mask sizes for the SEA-LONG oral nasal mask were available to choose from including large, medium and small. Based upon the current test experience if an individual purges frequently it is likely that he is wearing a mask that is too large. Wearing a mask that is too large results in a small air gap between the mask and the bridge of the nose that allows ambient air to leak into the closed circuit during inhalation. However, when a correctly fitted mask is used it was possible for 6 of the 11 subjects to complete the entire 60 min O_2 breathing period without conducting an additional purge.

Use of the insert T-bit in the oral nasal mask was expected to improve the seal/interface between the MBS 2000 and the subject and thus reduce potential leaks of ambient air into the closed circuit breathing loop. The results however showed no difference in leak rates or purge frequency between the two conditions. The main reason that the T-BIT condition did not improve the seal over the SL-MASK condition is that for some individuals the T-bit did not allow the SEA-LONG mask to make a good seal with their face and that during inhalation they may have inadvertently inhaled through their nose to introduce ambient air into the breathing circuit. In one subject the leaks associated with this problem were severe enough to require 7 purges over the 60 min rebreathing period (see graph for subject 9 in Appendix A).

Comments from some of the subjects suggested that the T-Bit pushed into their mouth and was uncomfortable, and that to maintain a good seal with the oral nasal mask they almost had to “deep throat” the T-bit. With their mouth biting the T-bit in the normal position a number of subjects were observed to show a small gap between the mask and their nose. Changing their oral nasal mask to a smaller size did not correct this problem since the T-bit then forced the mask of the end of the nose when the subject placed their mouth in the normal bite position on the mouthpiece. A solution to this problem would be to design the T-bit insert so that it could be inserted deeper into the valve “T” piece. Despite the above issue over half the subjects (n= 7) required only 1 additional purge and 4 subjects did not require any additional purges during the 60 min breathing period with the T-BIT.

Other reasons for purges included: 1) the mask detaching from the breathing valve “T” piece when tightening the head band straps, 2) subjects falling asleep during the 60 min breathing period and 3) leaks on inspiration around the O-ring seal of the CO_2 absorbent canister. After conducting the first few trials Dive Labs Inc resolved the first issue by supplying adapted “T” breathing valves. The adapted valves had a threaded end coupling over which a large support collar could be screwed against the inside of the mask to prevent the mask from detaching from the T valve when the head net straps were tightened.

During an actual treatment it is likely that some subjects will fall asleep while breathing on the unit. When this happens, the mask seal may be lost due to a relaxed head posture forcing the mask off the face. Even if a T-bit mouthpiece is used there will be a tendency for the subject to relax their lower jaw and inspire around the T-bit mouthpiece. This happened to at least one subject in the T-BIT trials resulting in a sudden leak of ambient air into the breathing circuit sufficient enough to prompt a purge. To avoid this problem it is recommended that the tender ensure that the subjects remain awake during the O_2 breathing periods.

Phase II: 60 fsw Testing of the modified MBS 2000

Methods

Subjects

Subjects were 11 U.S. Navy trained divers (mean ± SD age =37.0 ± 10.8 yrs, FVC 5.5 ± 0.7 L BTPS). Three of the divers had not participated in the previous surface tests. Subjects were briefed on the study objective and provided informed consent.

Apparatus

All the dive trials were performed in the Genesis hyperbaric chamber with the modified MBS 2000 in the T-BIT configuration as described in Phase I. To accommodate the additional oxygen requirements at 60 fsw the 255 liter capacity M9 oxygen cylinders were replace by D sized cylinders with a capacity of 425 liters at 25 °C and service pressure of 2015 psi. During the surface trials it became clear that the combination of the 70 psi over bottom pressure setting and the flow restrictor in the O_2 supply whip may result in excessive negative pressures during inhalation when conducting the purge procedures at depth. Consequently, the flow restrictor was removed from the supply whip of each MBS 2000 unit and the second stage over bottom pressure for the regulator was set at 125 psi for all the dive tests. The volume of oxygen used for each MBS 2000 was calculated from changes in bottle pressure measured using the same pressure transducers as described in phase I.

Two modified MBS 2000 units were each instrumented with an R10-DN oxygen sensor to continuously monitor the FiO_2. Output from each O_2 sensor was amplified by a prototype operational amplifier developed and manufactured by the Navy Experimental Diving Unit, Panama City, FL (see Figure 3). The amplified signal from each O_2 cell and output signal from each pressure transducer were connected through electrical penetrators in the chamber wall to the BIOPAC A/D recording system for online monitoring and storage.

Gas samples lines were connected to each MBS 2000 gas sample port and passed through the chamber wall to flow meters located outside the chamber. The micrometer valves on the external flow meters were set to provide a flow rate of 130 cc/min (sample line 1) and 180 cc/min (sample line 2) following volume expansion of the gas sample at 1 ATA. Low volume capillary lines connected to a “T” pipe-coupling that was attached to the output port of each flow meter permitted FiO_2 and $FiCO_2$ to be monitored continuously by the MGA 1100 Mass Spectrometer (sample line 1) or S-3A oxygen analyzer (Applied Electrochemistry) and CD-3A CO_2 analyzer (Applied Electrochemistry) (sample line 2). Gas samples measured by the Mass Spectrometer were automatically corrected to dry fractions. For the O_2 and CO_2 analyzer, gas samples were dried by passing the gas sample through a length of Nafion® membrane tubing as described in Fothergill (2005a). The small volume of gas drawn from the closed circuit breathing loop for gas sampling was not subtracted from the total oxygen use reported in the individual or group data.

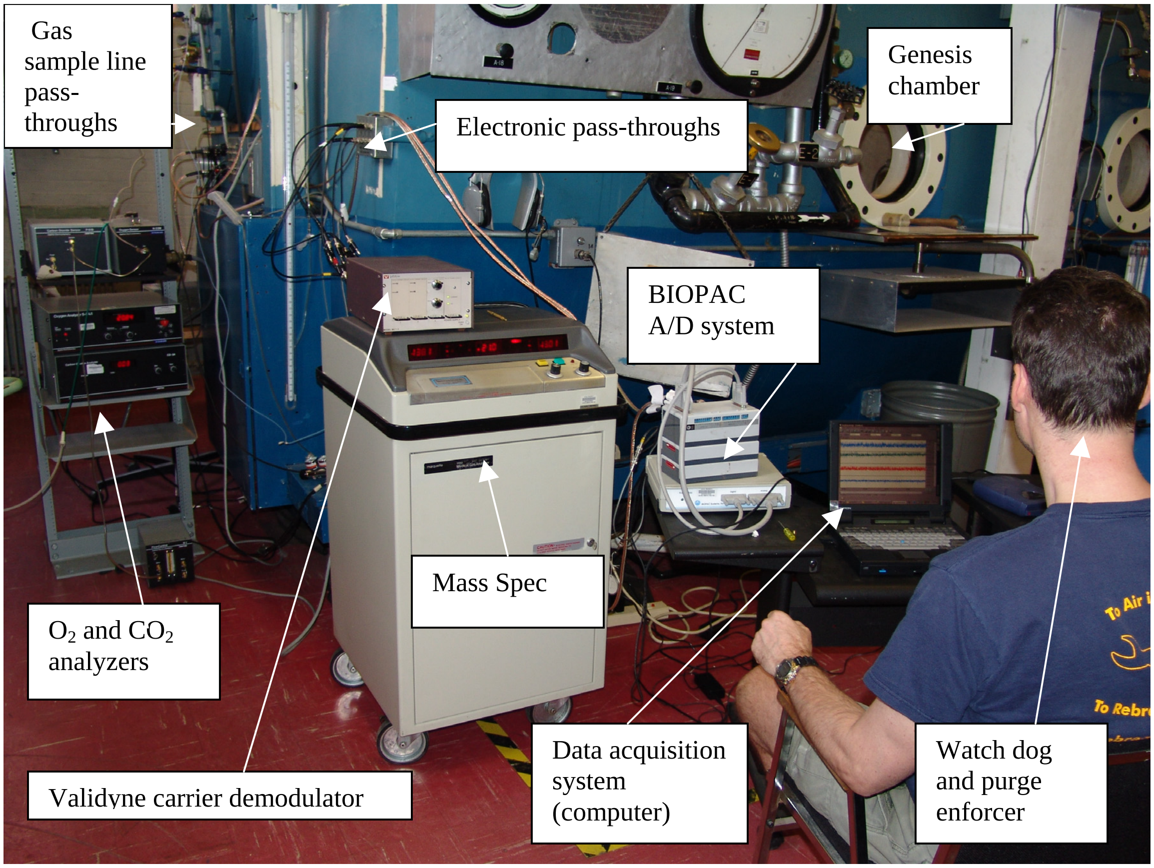

Figure 6: Experimental set up for the 60 fsw chamber trials

Procedures

After signing an informed consent each diver performed a single dive in the Genesis hyperbaric chamber to 60 fsw. The dive profile for the test subjects involved 60 minutes breathing chamber air at 60 fsw followed by two 20-minute oxygen breathing periods using the modified MBS 2000 and then decompression to surface. A five minute air break separated the two 20 minute O_2 breathing periods. The diver subjects and tender (who was locked into the chamber just prior to the first O_2 breathing period) were decompressed to the surface without a decompression stop. Although the decompression profile for the test subjects is outside the conventional US Navy Dive Tables the use of 40 minutes of oxygen breathing during the 106-minute bottom time at 60 fsw was sufficient for the dive to be considered a No-D dive. This dive profile was reviewed and approved by NAVSEA 00CM (letter from SEA 00C dated 5th Jan 2006 Ser 00CM/0001).

During the first 60 min period each R10-DN O_2 cell was calibrated using chamber air and close to 100% oxygen. For calibration with chamber air, the end cap containing the O_2 sensor was separated from the MBS 2000 unit. For calibration with a high oxygen fraction the O_2 cell was placed back into the MBS 2000 breathing circuit, the plunger for T- Valve at the mouthpiece was placed in the closed position, and the MBS 2000 manually purged by pressing the demand regulator cap with the slide valve in the open circuit position. The O_2 fraction within the closed circuit breathing loop was then sampled and measured by the mass spectrometer to provide the high oxygen gas fraction calibration value for the O_2 cell voltage output. Once the calibration procedure was completed the dial-a-breath was adjusted to so as to minimize cracking pressure but prevent free flow of oxygen.

At the start of the first O_2 breathing period subjects purged the MBS 2000 using the 10-breath open circuit method described in Phase I. At the end of the first 20 min O_2 breathing period they doffed the T-bit and oral nasal mask and closed the closed-circuit breathing loop by inserting the slide plunger into the "T"-valve. After a five-minute air break they donned the T-bit mouthpiece and mask, opened the slide plunger, and re-purged the MBS 2000 using the 5-breath open circuit method described in Phase I. During the O_2 breathing periods subjects were instructed to re-purge using the 5-breath open circuit method if their FiO_2 dropped below 0.80. Purge efficiency for the 5 and 10 breath purge procedures was determined by comparing the volume of O_2 used for the purge with the point sample FiO_2 achieved after 30 s of rebreathing.

Analysis
The initial 60-minute period on air was incorporated into the dive profile to provide a period where the subjects would on gas N_2. The additional N_2 taken up during the 60 minute air breathing period would then be expected to be subsequently off-gassed during the O_2 breathing periods. Given the exponential nature for N_2 off-gas kinetics it was expected that a greater volume of N_2 would be off-gassed during the first 20 min O_2 period compared with the second O_2 breathing period. It was thus hypothesized that the first 20 minute O_2 breathing period would lead to a lower mean FiO_2 and may require a greater number of purges to maintain a given FiO_2 fraction in the closed-circuit breathing loop compared with the second 20 minute O_2 breathing period. Thus the main statistical analysis involved paired t-tests to assess differences in oxygen consumption and mean FiO_2 levels between the two O_2 breathing periods. Paired t-tests were also used to assess differences in purge efficiency and purge volume between the 10 and 5 breath purge procedures at 60 fsw. Wilcoxon Matched Pairs Test was used to compare purge frequency between the two O_2 breathing periods. Data are presented as means ± SD for an n =11. Significance was set at $p<0.05$ for all tests.

Results

Individual Subject Data
Individual subject data for FiO_2 and oxygen consumption for the two 20 minute O_2 periods are summarized in Tables B1 and B2 in Appendix B together with the raw data presented in graphical form. To help in determining the pattern in the decline of FiO_2 with time (i.e. whether there was a slow decline or a precipitous drop in FiO_2 due to a leak) the figures are annotated with notes. When reviewing the data in the figures in Appendix B it should be noted that the subject doffed the MBS 2000 and took an air break between 1200 s and 1500 s.

In two subjects who were tested on the same dive (subjects 3 and 10) there was a temporary loss of output from the R10-DN cells towards the end of the first O_2 period. The loss of signal was found to be due to a loose wire in one of the operational amplifier circuits. Since the operational amplifiers were connected in series, output from both R10-DN O_2 cells were affected. It should be noted that the prototype operational amplifier shown in Figure 3 was incorporated into the MBS 2000 without the top cover. This was necessary because it was found that due to limited clearance between the circuit board and the top cover, if the top cover was in place it compressed some of the circuit board components and shorted the operational amplifier. For future production versions of this operational amplifier it is recommended that it be ruggedized and firmly attached to the MBS 2000 unit in a place where it is unlikely to be damaged. Furthermore, it is recommended that if multiple R10-DN O_2 cells are to be monitored at the same time that interconnectivity/monitoring of the O_2 cells is not compromised if one unit is shorted or non-functional.

Comparison of R10-DN (wet) FiO_2 and dry FiO_2 readings
Differences between the wet FiO_2 as measured by the R10-DN and the dry FiO_2 as measured by the mass spectrometer or Applied Electrochemistry paramagnetic O_2 analyzer are shown for the first and second 20 minute O_2 period in Tables B1 and B2, respectively. The mean wet FiO_2 was 0.041 lower than the dry fraction during the first 20 min O_2 period and only 0.024 lower during the second 20 min O_2 period. As in the surface trials the lower FiO_2 measured by the R10-DN reflects the fact that the oxygen cell does not correct for water vapor pressure. The large differences between wet and dry FiO_2 found at the end of the surface trials were not evident in the shorter depth trials. Although a different amplifier system was used during the depth and surface trails, previous experiments using the DC Gould amplifier suggest that amplifier drift was an unlikely cause of the diverging FiO_2 differences between the Mass spec and R10-DN readings. A more likely explanation for the aforementioned difference is that during the depth trials the CO_2 canister temperature and thus the gas temperature did not have time to reach the high temperatures noted at the end of the surface trials.

Group Analysis
Table 2 compares the group mean data collected during the first 20-minute O_2 breathing period with the data from the second O_2 breathing period. These results show that the 10-breath open circuit purge used 45% more O_2 than the 5-breath purge ($p<0.05$) but also raised the starting FiO2 to a higher level ($p<0.05$). Despite differences in purge volume and starting FiO_2 between the two purge procedures both purge procedures achieved a mean starting FiO_2 above 0.95. Thus if oxygen usage is a concern the 5 breath purge procedure could be used for the initial purge to reduce O_2 volume requirements. The large volume use of the 10 breath purge compared to the five breath purge clearly contributed to the greater volume usage over the first 20 min O_2 period compared to the second 20 min O_2 breathing period.

Table 2: Comparison of performance for the modified MBS 2000 between the first and second O_2 breathing trials at 60 fsw. For the dive tests the MBS 2000 was used with T-BIT mouthpiece and SEA-LONG oral nasal mask. Data are mean ± SD (n=11) * = Significant at p<0.05 (paired t-test).

Variable	First O_2 Period	Second O_2 period	p
Purge volume (10 breath vs 5 breath) (liters)	81.5 ± 17.9	44.8 ± 9.7	<0.001*
Starting FiO_2 x 100 (%)[1]	97.8 ± 1.2	95.6 ± 2.4	0.002*
Oxygen usage over 20 min inclusive of initial purge (liters)	110.2 ± 39.6	62.1 ± 13.9	<0.001*
Oxygen usage over 20 min exclusive of initial purge (liters)	28.9 ± 28.0	17.3 ± 10.8	0.092
Mean FiO_2 x 100 over 20 min (%)[1]	93.4 ± 2.1	92.5 ± 2.8	0.203
Mean number of additional purges	0.45 ± 0.69	0.18 ± 0.40	0.109

[1] FiO_2 values are given as dry fractions x 100

When the initial purge volume is subtracted from the total volume of oxygen used during the 20 min breathing periods there was no significant difference in oxygen volume requirements between the first and second 20 min O_2 periods. Furthermore, both the mean FiO_2 over the 20 minutes and mean number of additional purges were not significantly different between the first and second O_2 breathing periods. This suggests that variability in mask fit and leaks of chamber air into the closed circuit breathing loop are of greater concern to the FiO_2 level within the breathing loop and to the purge frequency than the volume of N_2 entering the closed circuit breathing loop from the lungs due to off gassing.

When the mean oxygen volume used during the 60 fsw trails are converted to equivalent surface pressure volumes (i.e. divided by 2.82 ATA) and presented as rates of O_2 use/man, the first 20 minute O_2 period used approximately 2.0 liters/min/man and the second O_2 period used 1.1 liters/min/man. The high oxygen usage during the first period reflects the higher O_2 volume used for the initial 10-breath purge procedure.

It should be noted that the mean FiO_2 over both 20-minute breathing periods exceeded 90%. The mean FiO_2 over the first 30 minute period is almost identical to that observed during the initial acceptance testing of the Diving Systems International (DSI) closed circuit rebreather, a forerunner of the current MBS 2000 (White et al., 2000). During the initial evaluation of the DSI unit using 10 submariners and 10 divers the mean ± SD FiO_2 during a 20 min O_2 breathing period at 60 fsw was 92.8 ± 0.88 %.

In the current dive trials during the first O_2 breathing period only 4 subjects required an extra purge while during the second 20 min breathing period only 2 subjects needed an additional purge. Those who needed an extra purge reported the same problem with mask fit as was described in Phase 1 (i.e. that the T-bit mouthpiece prevented a good seal with the oral nasal mask.

Conclusions and Recommendations

In conclusion, the slide valve modification significantly improved performance of the MBS 2000 unit and is recommended to be included as a permanent modification. If this modification is adopted the current strap arrangement for support of the MBS 2000 should be modified to avoid the possibility of the support straps being caught in the slide valve and preventing the sleeve of the slide valve from reaching the full closed circuit position. Use of the slide valve permitted the entire MBS 2000 breathing loop to be purged, which resulted in a more efficient and simpler purge procedure. Both the 10 and 5 breath open circuit purge procedures were able to achieve a starting FiO_2 >0.95. The 10 breath open circuit purge procedure may be more appropriate for those individuals who are unable to conduct large breaths due to lung injury or smoke inhalation, or who are breathing but unconscious and require administration of oxygen. For individuals who are capable of conducting large tidal breaths during a purge, the 5-breath procedure provides an adequate purge. If the 5-breath purge procedure is adopted for all purges and re-purges are conducted when FiO_2 levels drop below 0.80 then the estimated O_2 usage over a 20 minute O_2 breathing period will be 1.1 liters/min/man at 1 ATA.

The use of the SEA-LONG mask and the SEA-LONG mask with T-BIT insert worked equally well and together with the new hose clamps helped maintain a higher FiO_2 level within the breathing circuit compared to when the original mask and MBS 2000 was used. If the SEA-LONG mask is to be adopted it is important that the T valve be adapted to prevent the mask from detaching accidentally when tightening the head net straps. Use of the T-bit mouthpiece has the potential to reduce leaks of ambient air into the breathing circuit for subjects who have difficulty obtaining a good seal with an oral nasal mask due to either facial anthropometry incompatibilities or excessive facial hair. However, the current arrangement with the SEA-LONG oral nasal masks needs slight modification to ensure the T-bit mouthpiece insert permits a reasonable seal with the oral nasal mask for all subjects. Specifically, the T-bit insert mouthpiece needs to be capable of inserting at least a further 1 cm into the T-valve assembly to improve comfort and provide a good mask fit for the majority of subjects.

The findings indicate that the main causes of leaks into the closed-circuit breathing loop are from an incompatible match between the mask and facial anthropometry (i.e. choosing the wrong mask size) or accidentally breaking the seal with the oral nasal mask and allowing ambient air to be inhaled (i.e. scratching the face or falling asleep). A minor source of leaks of ambient air into the circuit may occur in some units due to a poor O-ring seal at the CO_2 canister. Inspiratory leaks may also occur if high negative pressures are required to initiate flow from the regulator. High inspiratory pressures will compound any small leaks due to a poor O-ring seal at the CO_2 canister in addition to any leaks that may occur around the sides of the oral nasal mask. To minimize these potential leak sources it is recommended that the over bottom pressure be set at the manufacturers recommended setting (i.e. 125 psi over bottom pressure) and the flow restrictor be removed from the oxygen supply whip.

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Appendix A

Individual Subject Data for Surface Trials

The data shown in Tables A1 and A2 summarize the individual subject data shown in the following plots of F_IO_2 versus time for the two mask conditions, SEALONG Oral nasal mask only, and SEALONG Oral nasal mask plus T-bit. The gas sample delay from the F_IO_2 data measured using the Mass spec was identical to the response time for the R10-DN. The individual subject plots that follow Tables A1 and A2 were generated by resampling the raw BIOPAC data files (original sample rate = 50 Hz) at a 1 Hz sample rate and then importing the resampled data into Statistica (Statsoft™ Tulsa, OK) software for plotting. Each subject's data are listed by subject number with subject # 1-3, 8-11, and 15 representing the diver subjects and subject # 4-7 and 12-14 representing the submariner subjects. Note that the initial purge was a 10-breath purge, and that all subsequent purges were 5 breath purges (see methods section). All volumes are given in standard liters at 1 ATA and 25 °C. Specific notes on the individual data (i.e. reasons for sudden drops in F_IO_2) are given in the appropriate individual graphs.

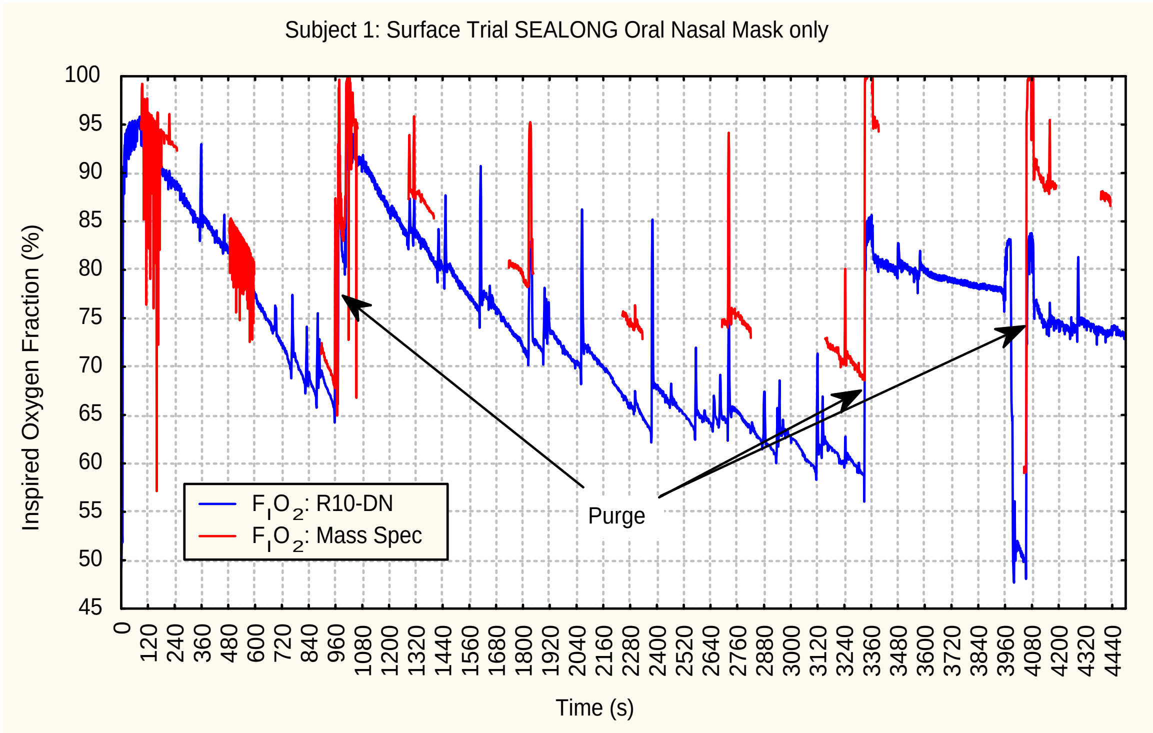
Table A1. Individual subject data for the surface trials using the SEALONG Oral nasal mask only.

Subject #	10 breath purge Volume (l)	5 breath purge Volume (l)	Total O_2 consumption over 60 min (l)	Mean R10-DN F_IO_2 over 60 min (%)[1]	# Additional Purges over 60 min
1	25.3	11.1	74.0	74.9	2
2	28.3	18.7	43.5	87.4	0
3	23.1	15.4	59.1	79.3	1
4	15.0	10.1	56.3	74.2	3
5	15.8	10.9	84.5	76.3	5
6	11.0	6.3	93.5	73.1	7
7	27.8	14.3	41.9	80.5	0
8	20.5	11.8	41.4	86.0	0
9	22.4	12.5	72.5	79.9	3
10	24.0	14.7	57.3	81.2	1
11	14.5	15.9	59.7	91.1	3
12	8.9	12.3	80.2	79.0	7
13	11.1	7.8	29.1	71.5	0
14	9.7	6.8	30.6	74.7	0
15	24.9	13.9	48.2	82.6	0
Mean	18.8	12.2	58.1	79.4	2.1
SD	6.8	3.5	19.6	5.6	2.5

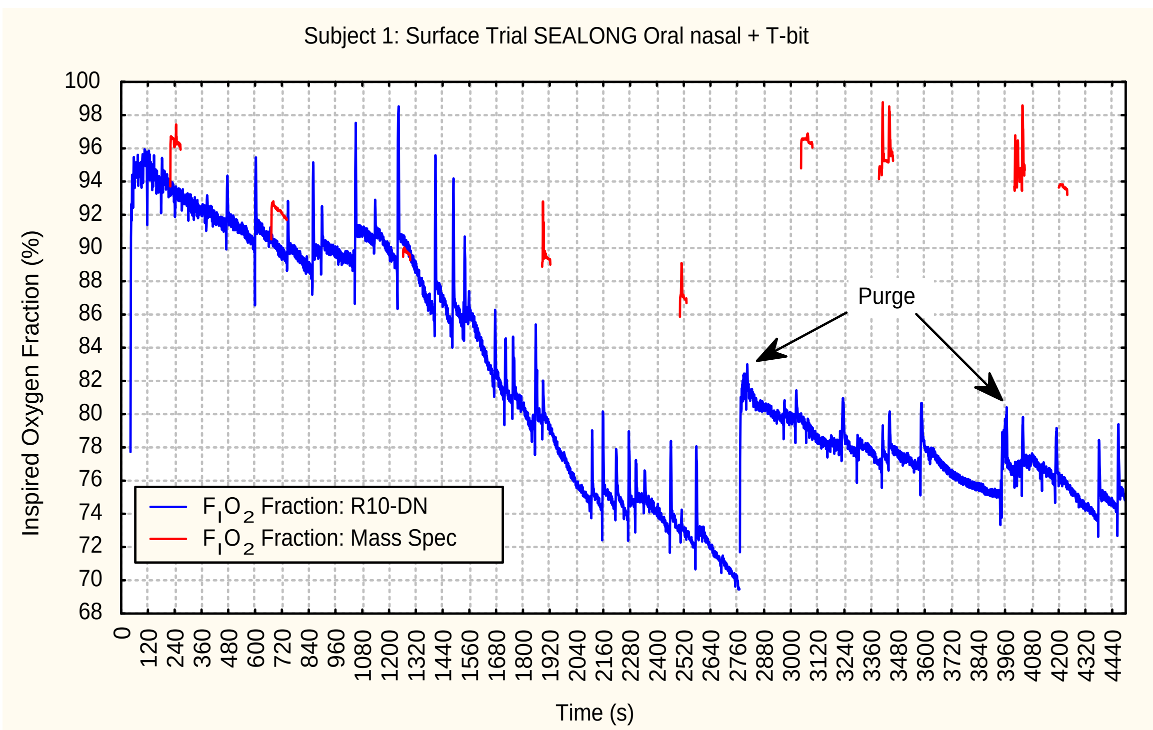
Table A2. Individual subject data for the surface trials using the SEALONG Oral nasal mask plus T-bit.

Subject #	10 breath purge Volume (l)	5 breath purge Volume (l)	Total O_2 consumption over 60 min (l)	Mean R10-DN F_IO_2 over 60 min (%)[1]	# Additional Purges over 60 min
1	29.1	10.6	64.7	82.9	1
2	37.1	13.2	64.4	87.0	1
3	19.9	7.8	53.3	79.1	1
4	12.5	7.2	44.9	80.7	1
5	22.1	12.7	56.8	83.5	2
6	16.8	9.6	35.9	82.0	0
7	12.0	11.3	32.0	86.5	1
8	18.6	14.9	41.8	76.5	1
9	20.2	10.8	111.0	80.5	7
10	26.8	13.0	86.3	83.2	1
11	22.5	18.7	49.0	79.7	1
12	16.7	14.2	121.5	79.7	0
13	10.6	9.2	33.7	70.3	0
14	10.5	5.7	46.6	79.8	2
15	23.0	12.7	46.7	84.3	0
Mean	19.9	11.4	59.2	81.0	1.3
SD	7.4	3.3	27.0	4.1	1.7

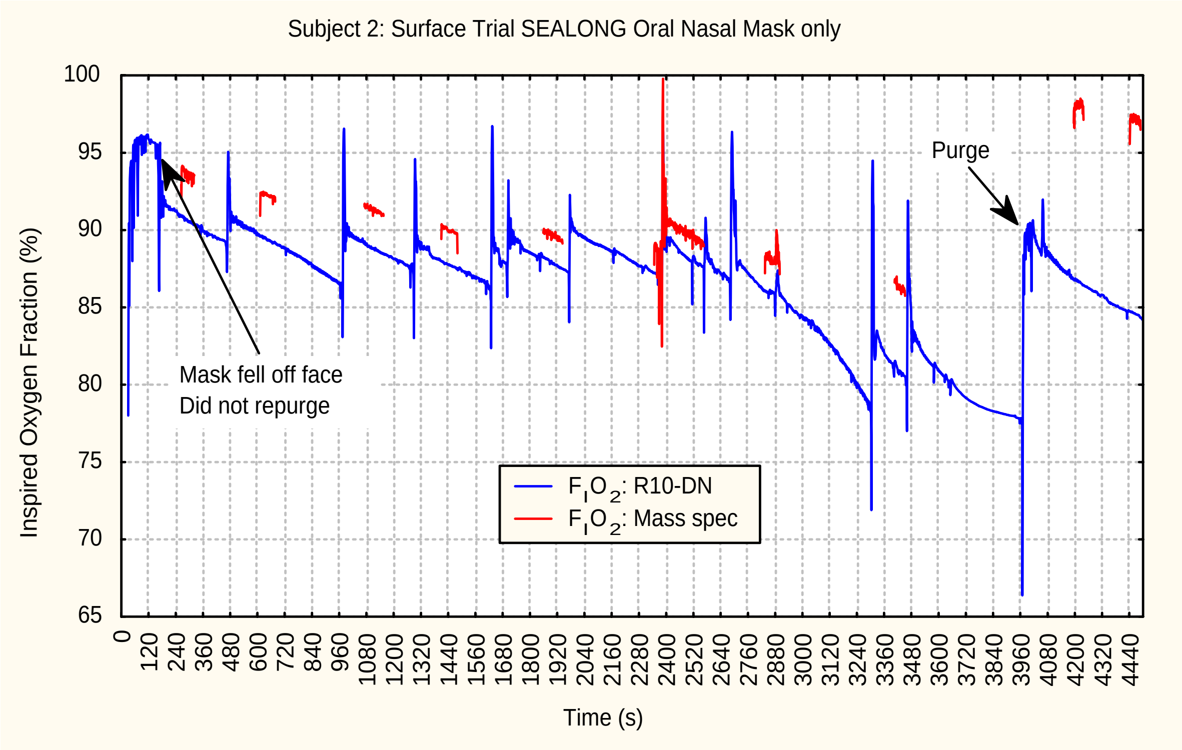
[1] F_IO_2 measurements taken with the R10-DN oxygen cell are wet fractions (i.e. are not adjusted for water vapor pressure).



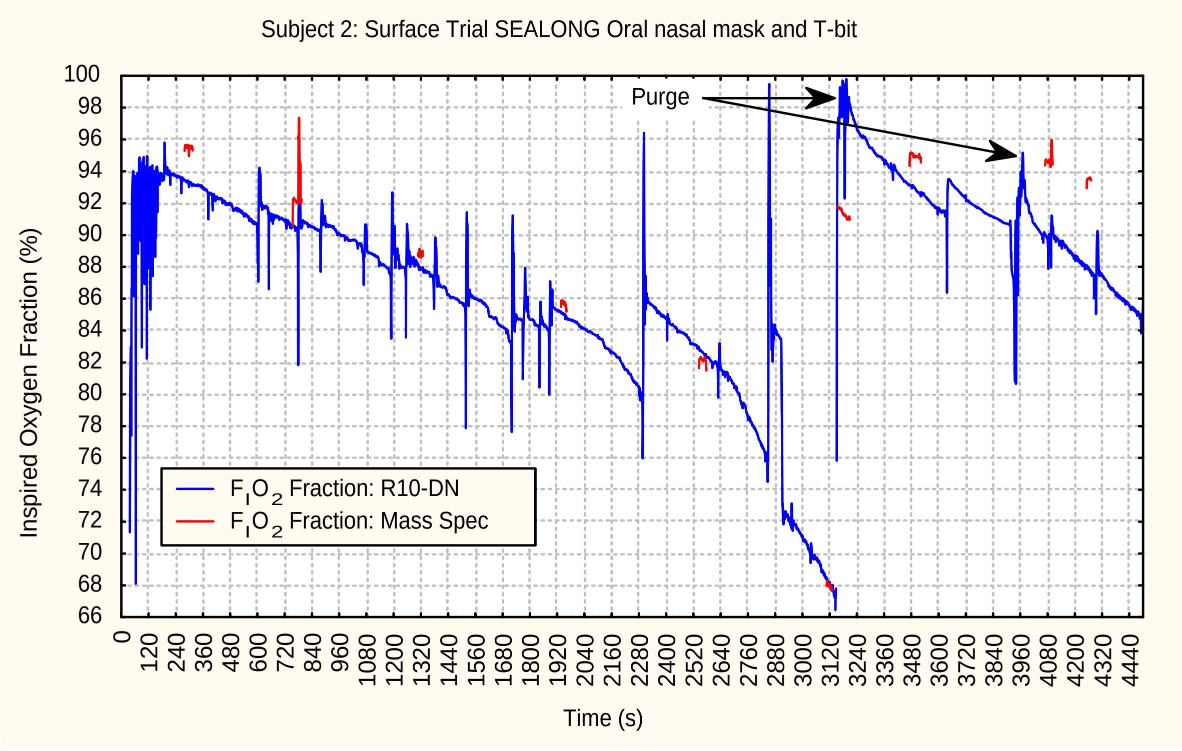
Subject 1: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass Spec
Purge



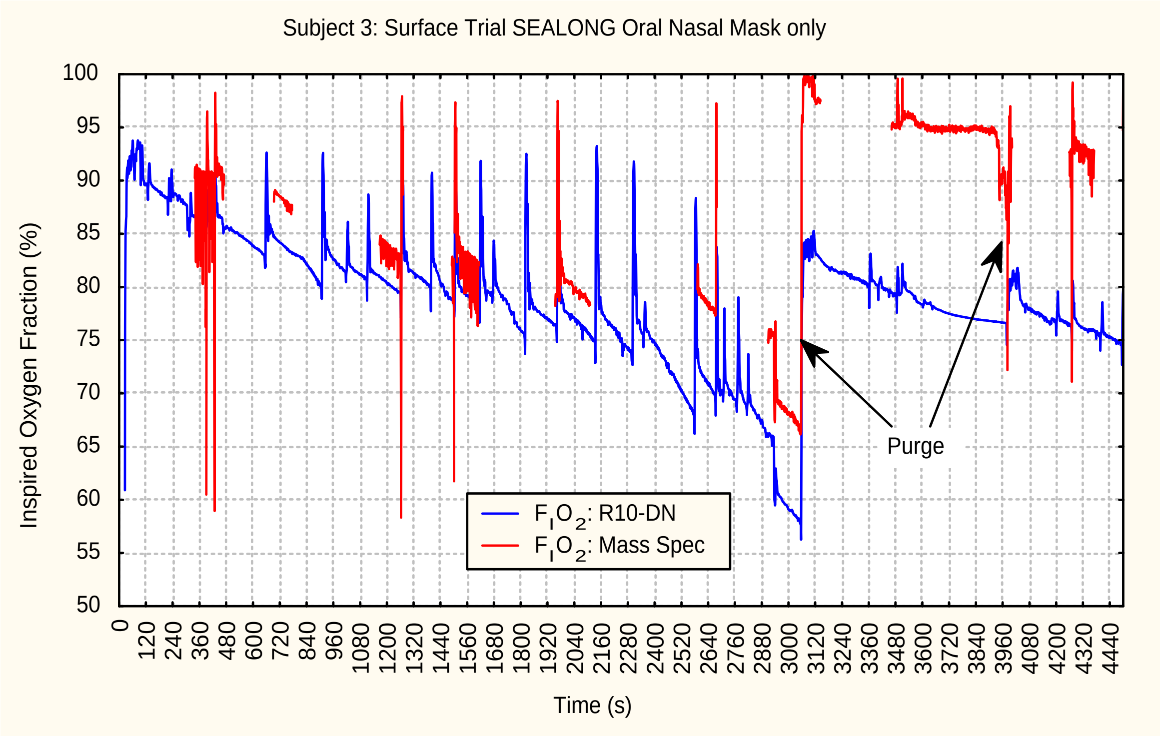
Subject 1: Surface Trial SEALONG Oral nasal + T-bit
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2 Fraction: R10-DN
F_IO_2 Fraction: Mass Spec
Purge

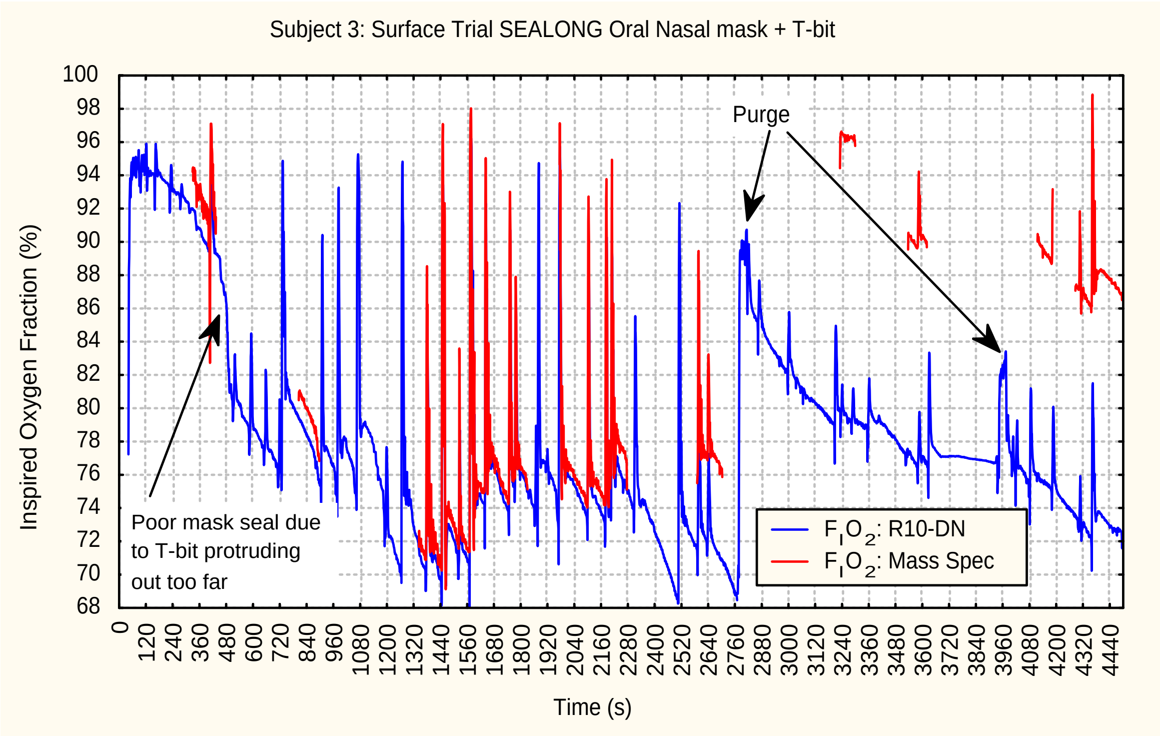


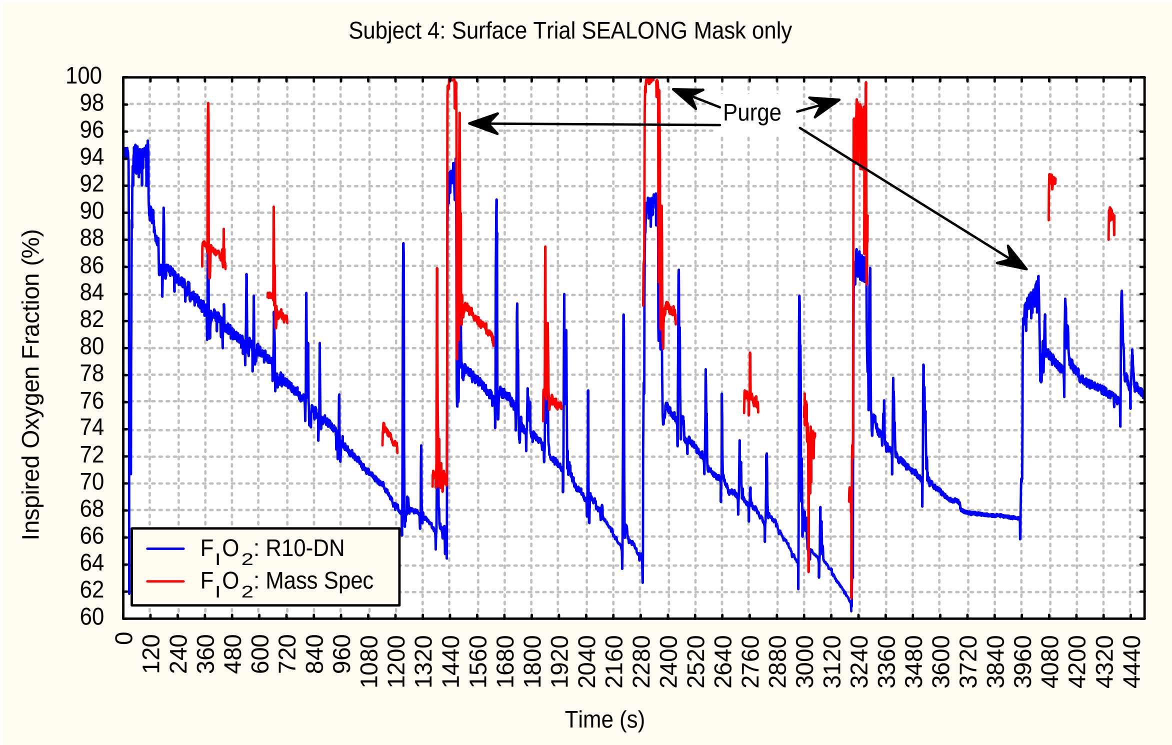
Subject 2: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Mask fell off face
Did not repurge
Purge
F_IO_2: R10-DN
F_IO_2: Mass spec

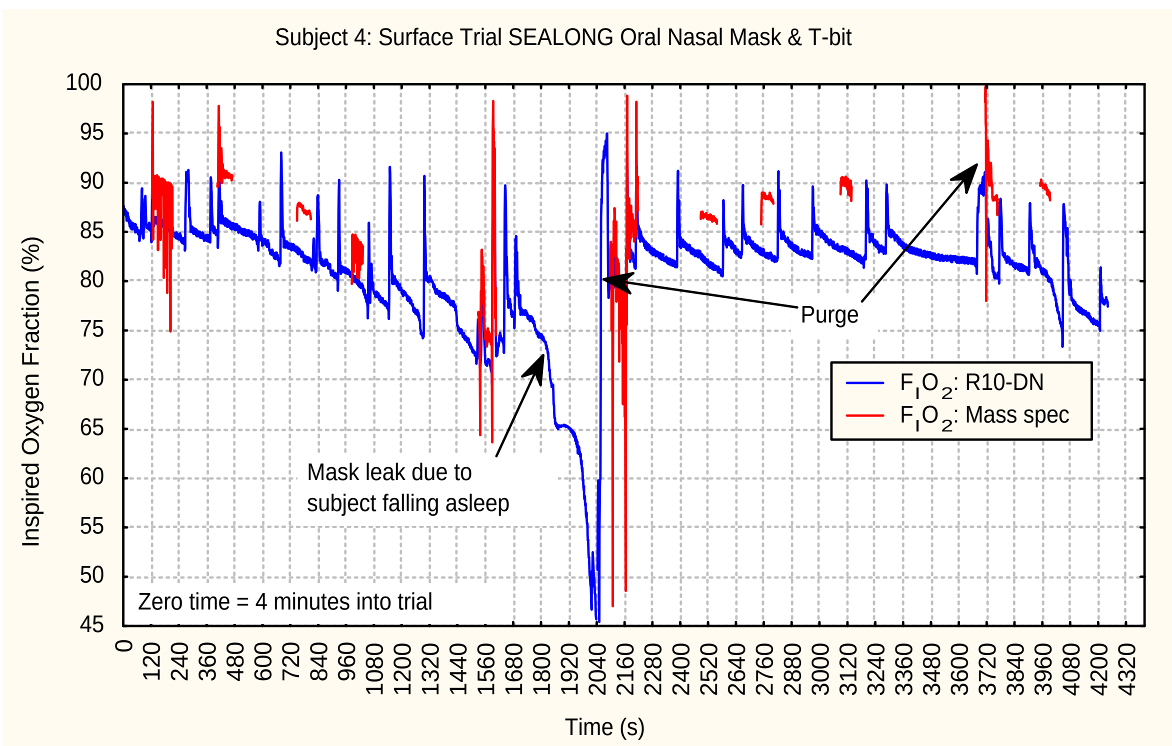


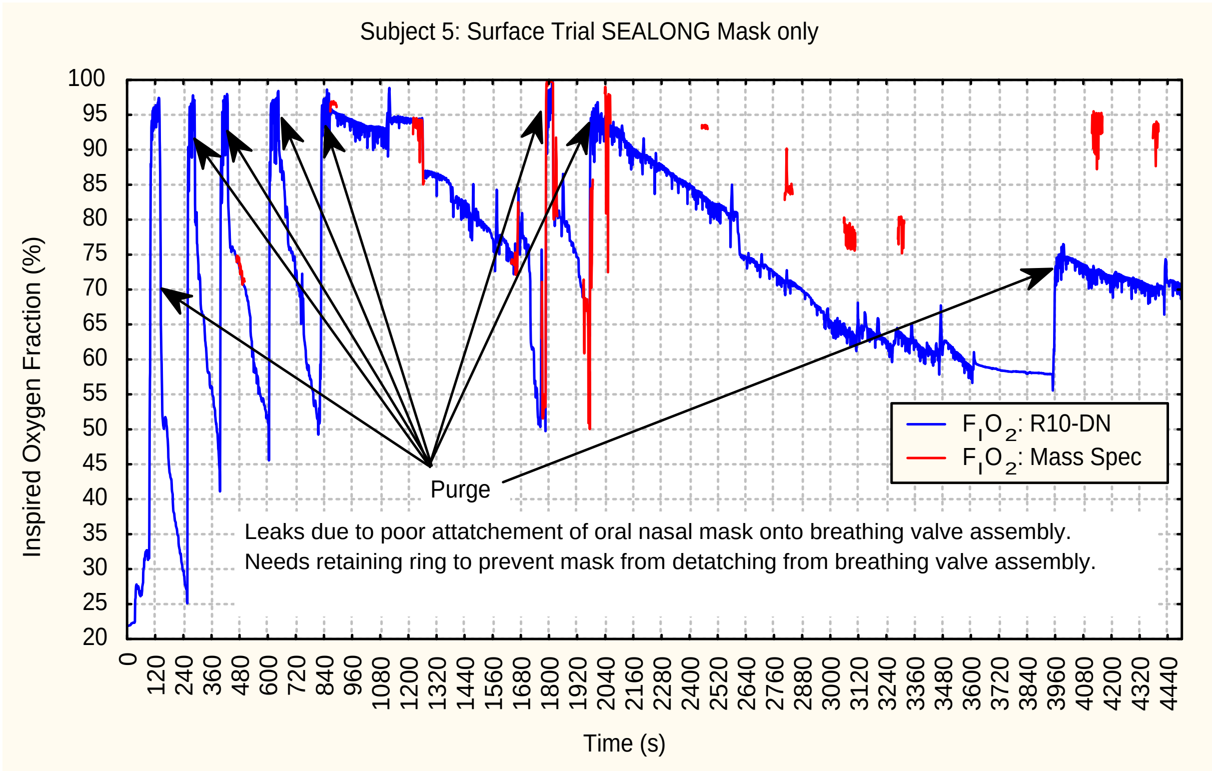
Subject 2: Surface Trial SEALONG Oral nasal mask and T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
F_IO_2 Fraction: R10-DN
F_IO_2 Fraction: Mass Spec

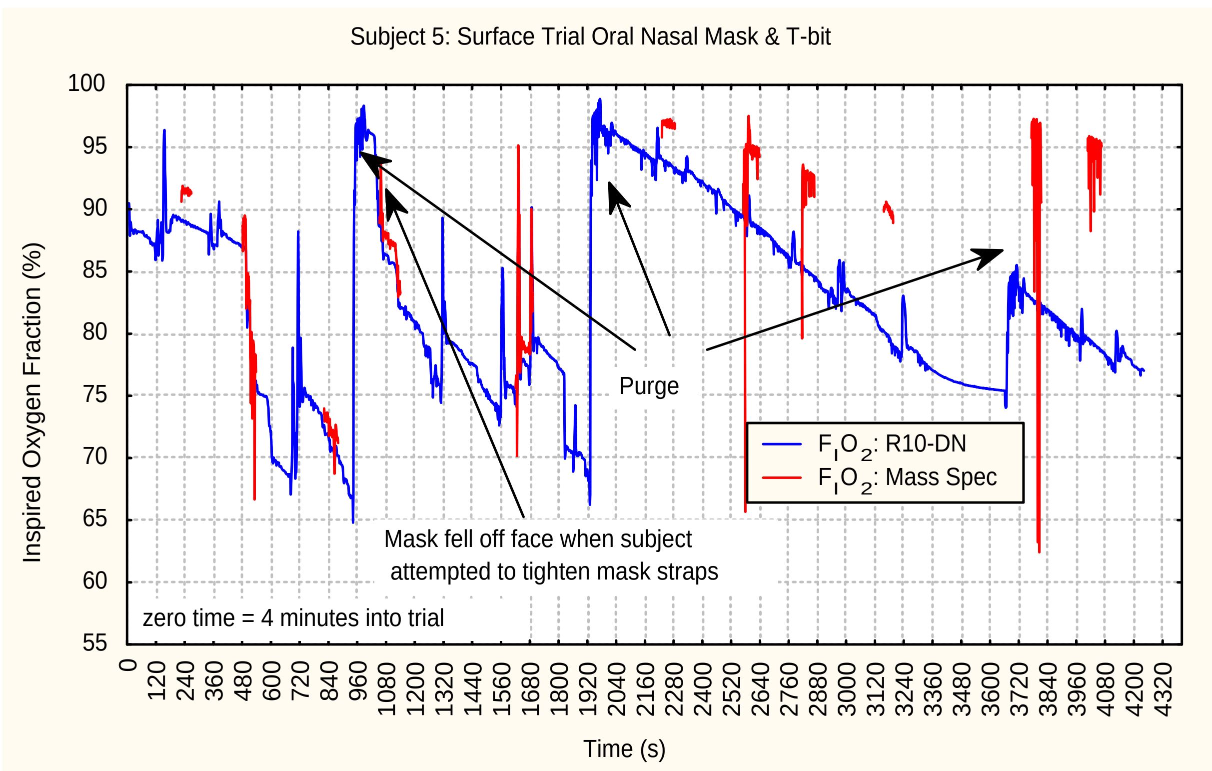

Subject 3: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec

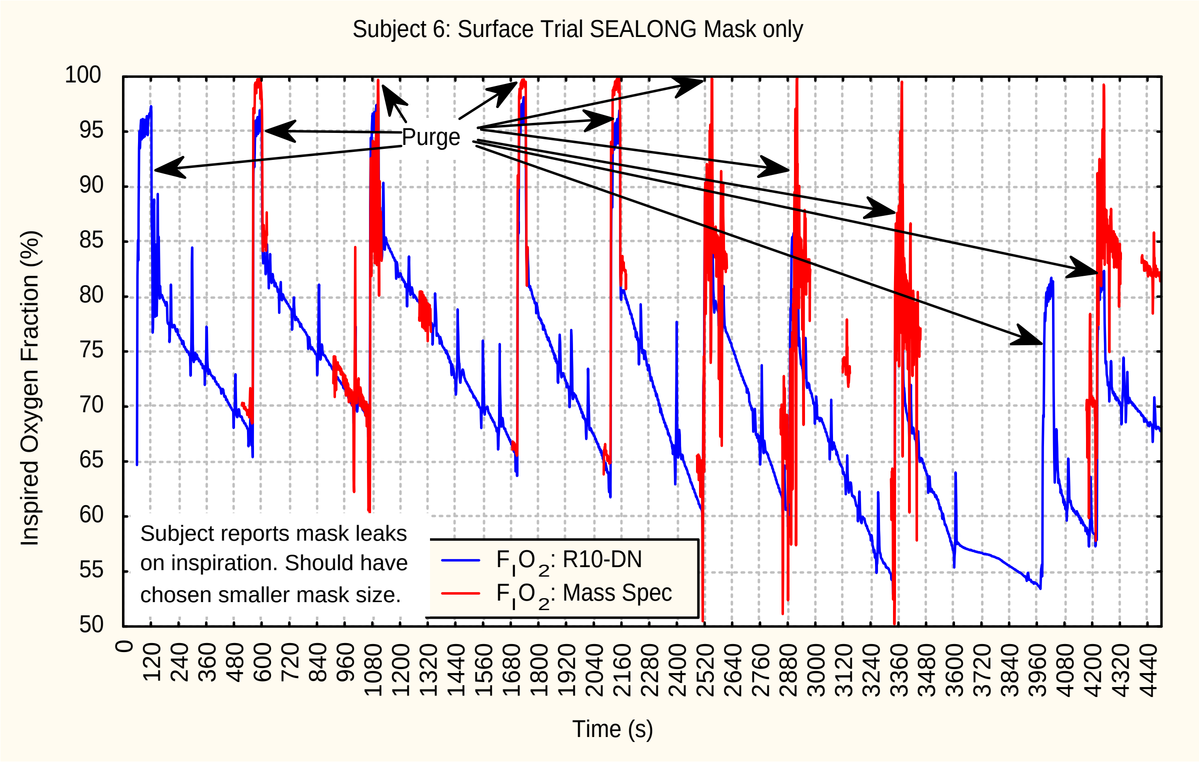

Subject 3: Surface Trial SEALONG Oral Nasal mask + T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
Poor mask seal due to T-bit protruding out too far
F_IO_2: R10-DN
F_IO_2: Mass Spec


Subject 4: Surface Trial SEALONG Mask only
Purge
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass Spec

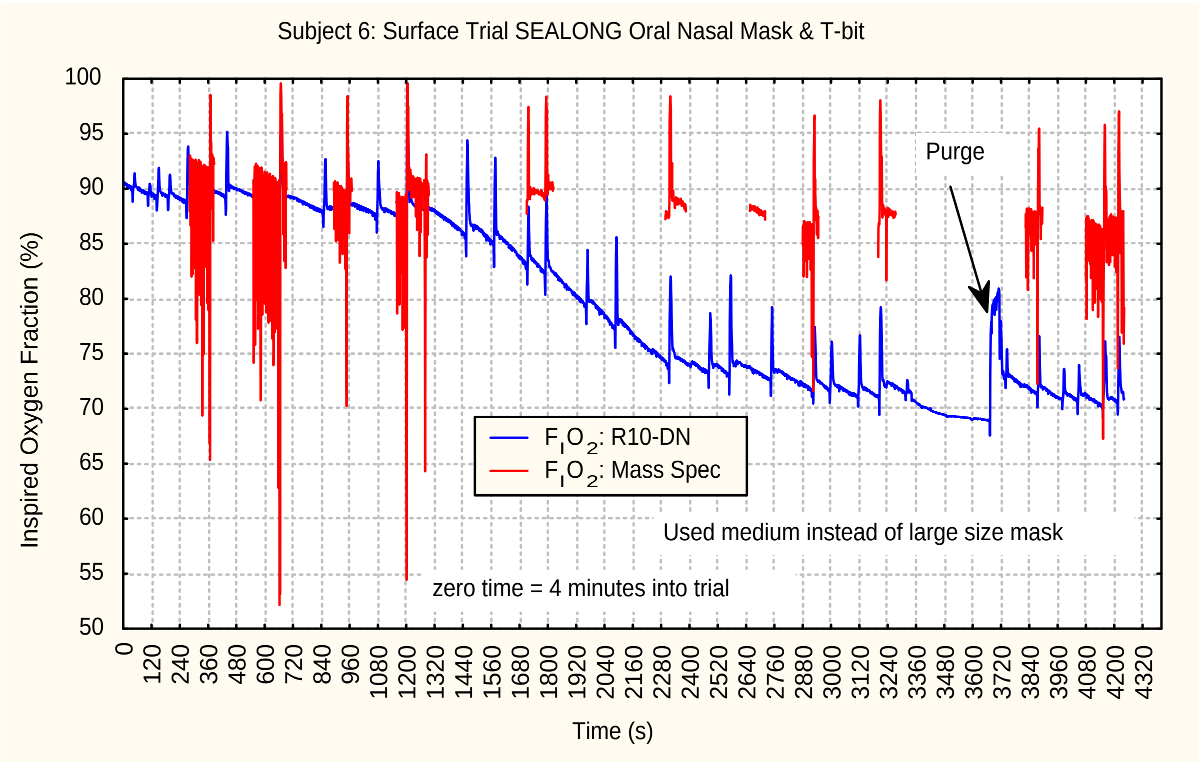

Subject 4: Surface Trial SEALONG Oral Nasal Mask & T-bit
Purge
Mask leak due to
subject falling asleep
Zero time = 4 minutes into trial
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass spec


Subject 5: Surface Trial SEALONG Mask only
Inspired Oxygen Fraction (%)
Time (s)
Purge
Leaks due to poor attatchement of oral nasal mask onto breathing valve assembly.
Needs retaining ring to prevent mask from detatching from breathing valve assembly.
F_IO_2: R10-DN
F_IO_2: Mass Spec

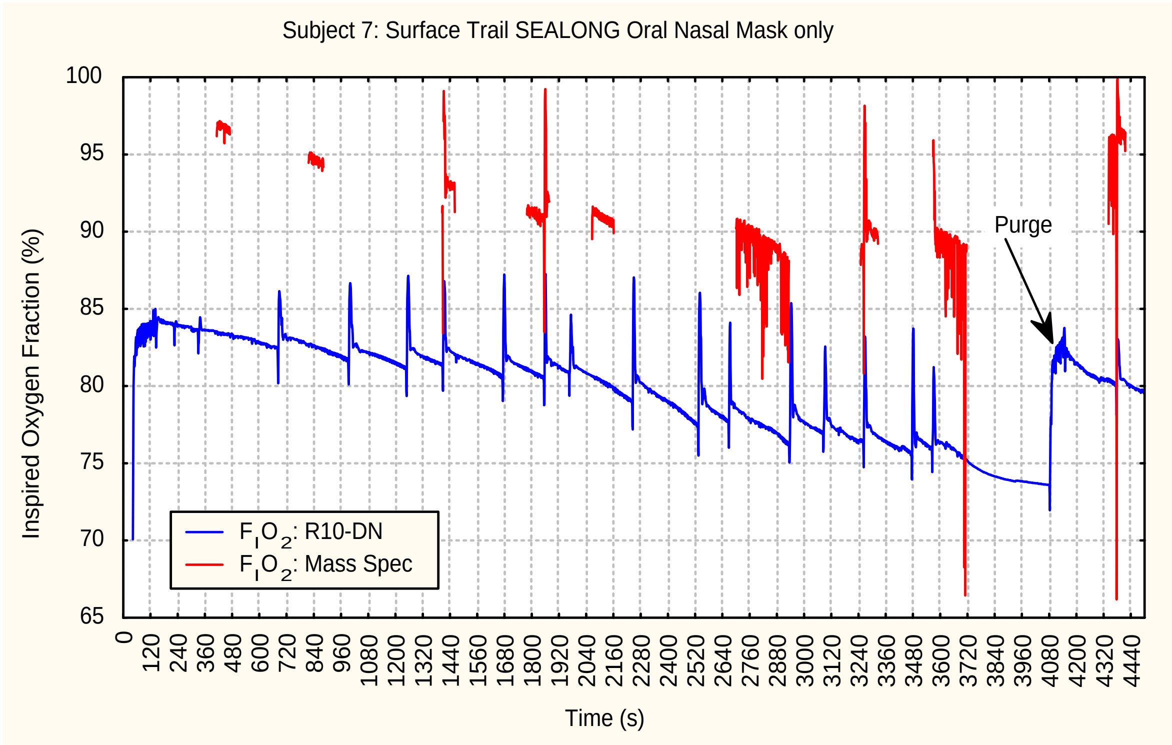

Subject 5: Surface Trial Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
Mask fell off face when subject attempted to tighten mask straps
zero time = 4 minutes into trial
F_IO_2: R10-DN
F_IO_2: Mass Spec



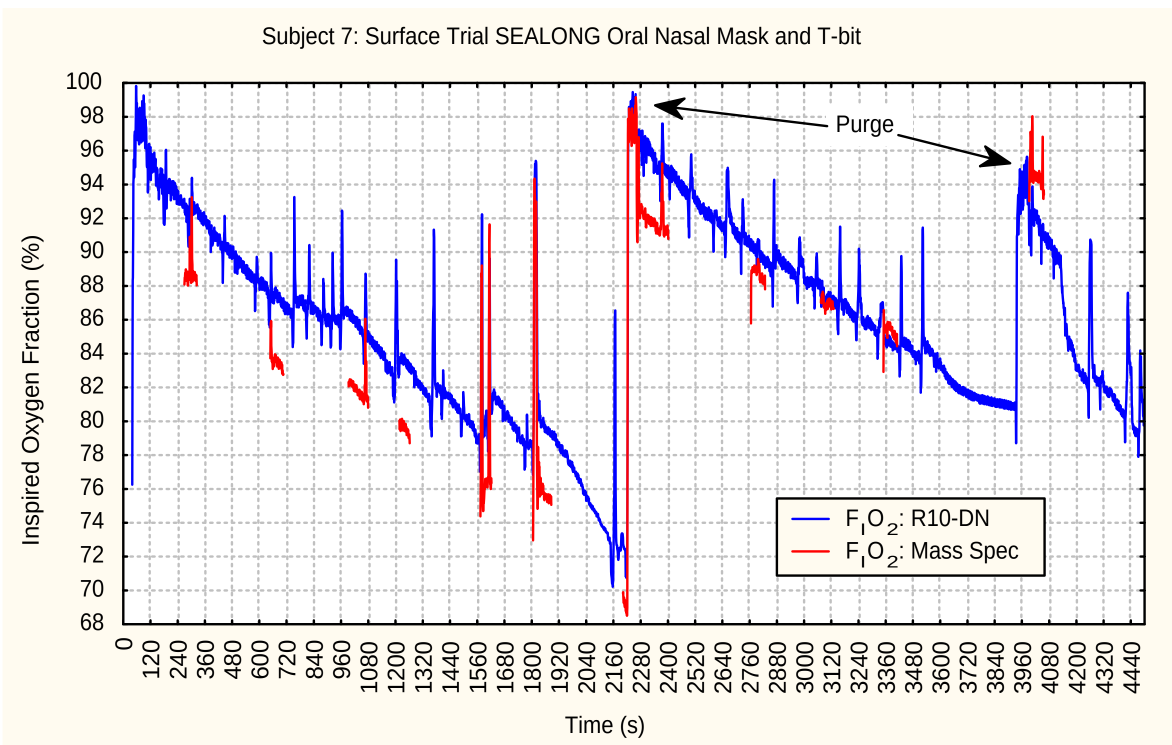
Subject 6: Surface Trial SEALONG Mask only
Inspired Oxygen Fraction (%)
Time (s)
Purge
Subject reports mask leaks on inspiration. Should have chosen smaller mask size.
F_IO_2: R10-DN
F_IO_2: Mass Spec



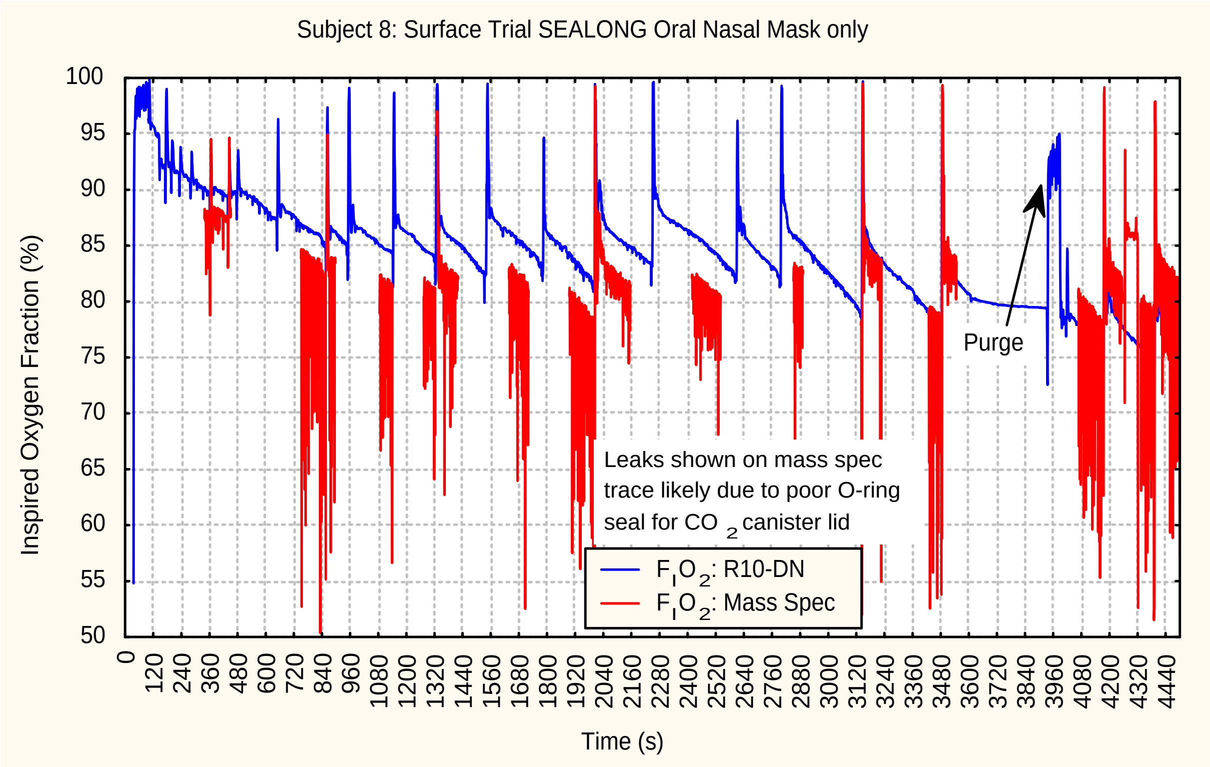
Subject 6: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec
Used medium instead of large size mask
zero time = 4 minutes into trial

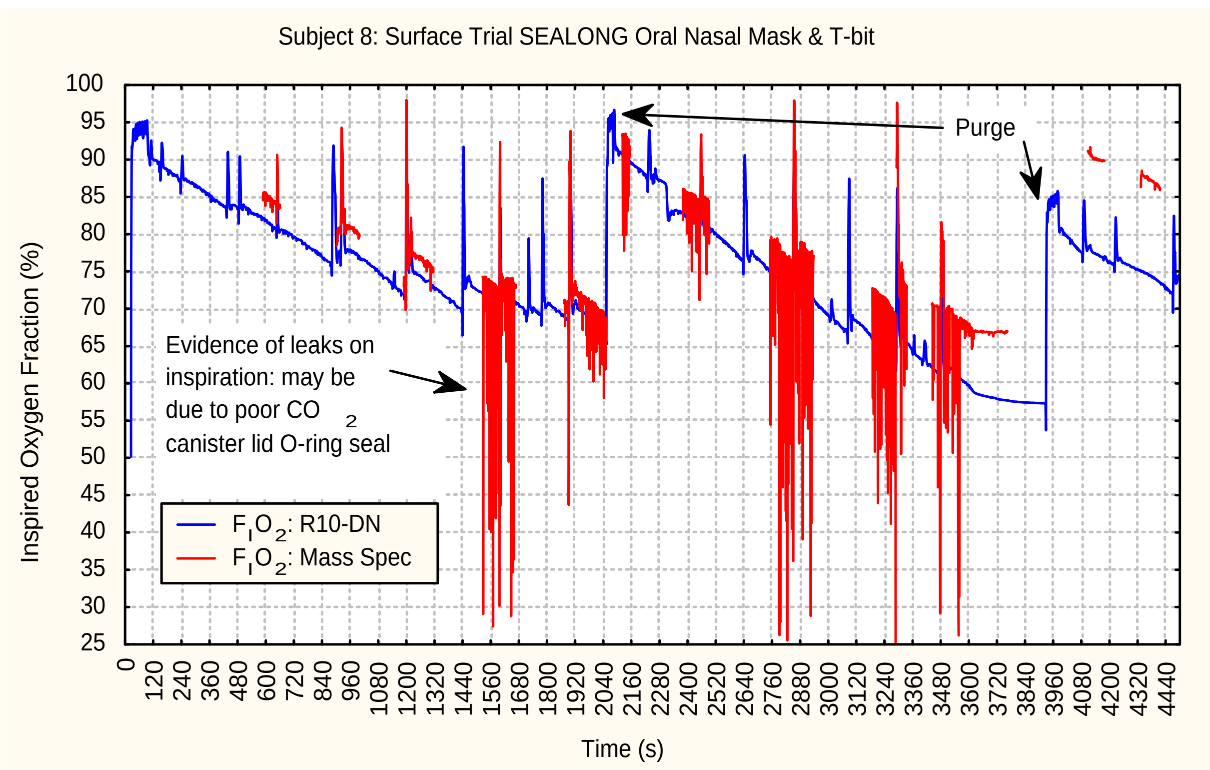


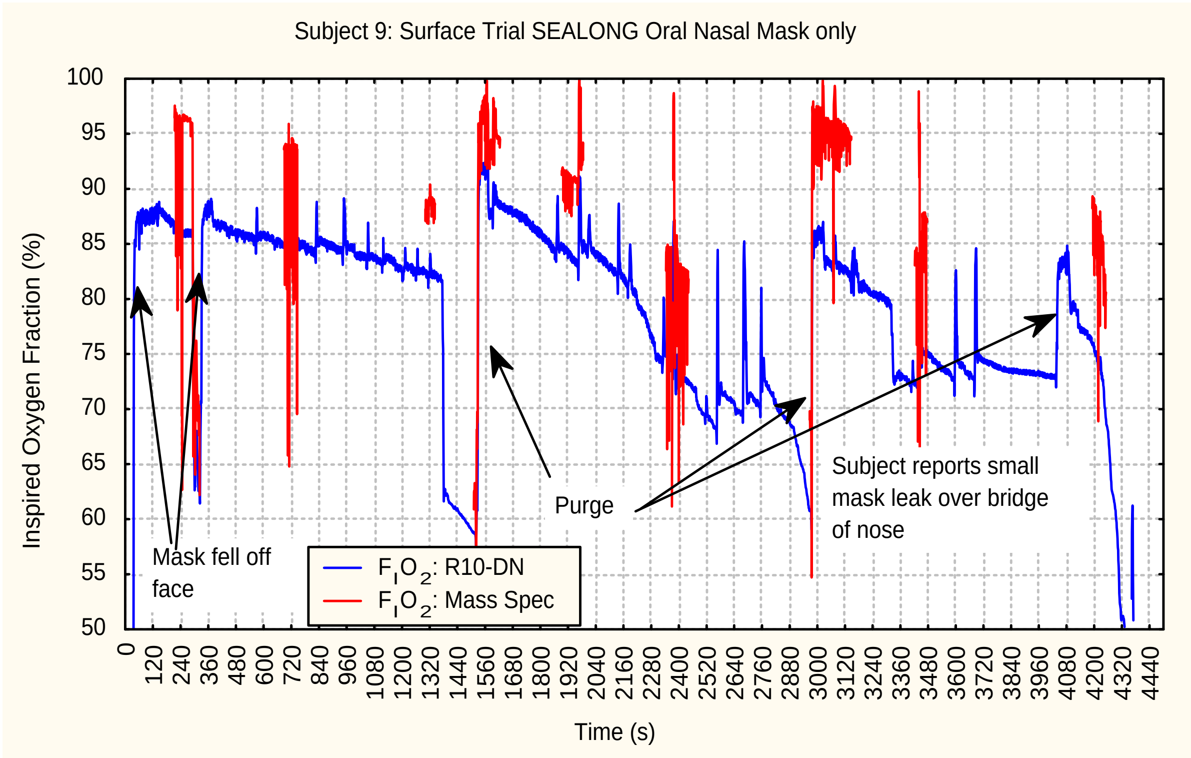
Subject 7: Surface Trail SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec

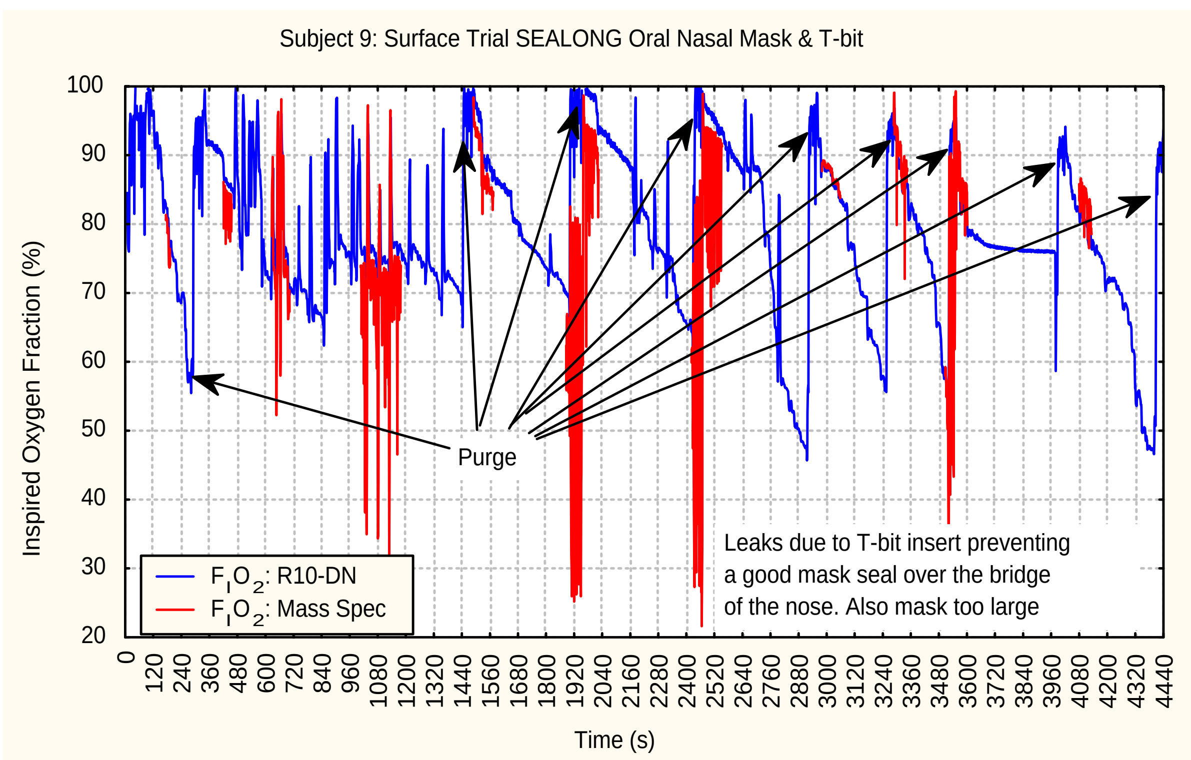


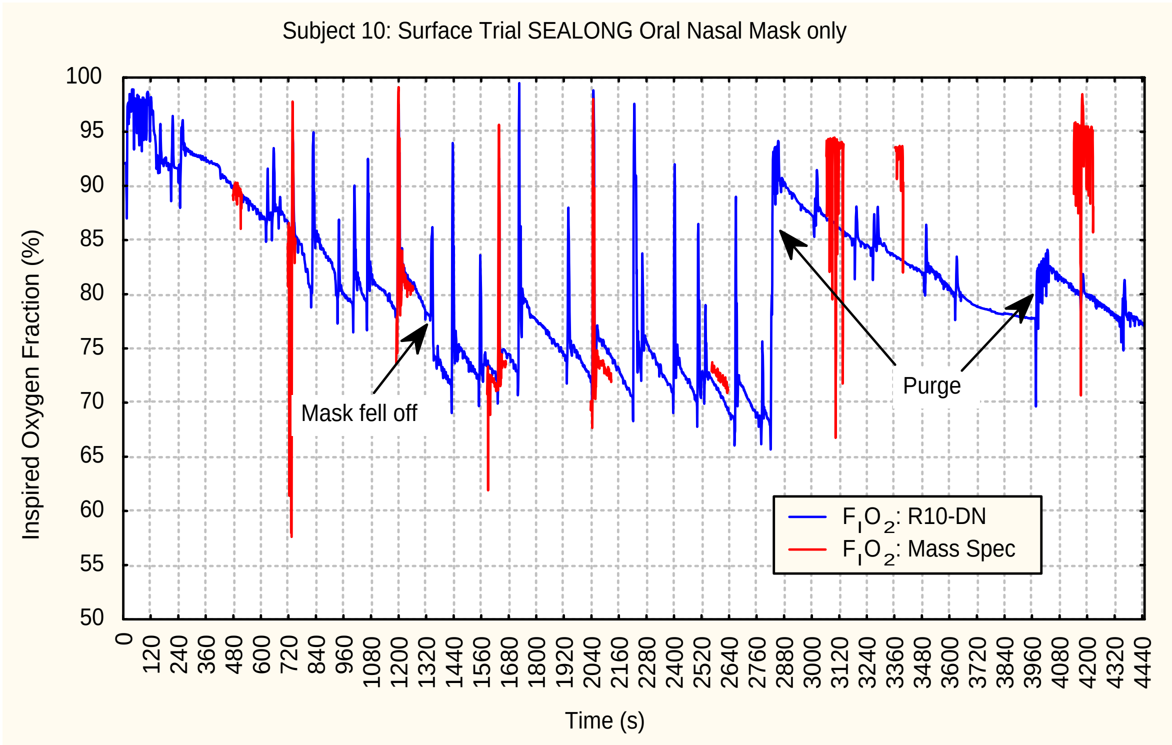
Subject 7: Surface Trial SEALONG Oral Nasal Mask and T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec

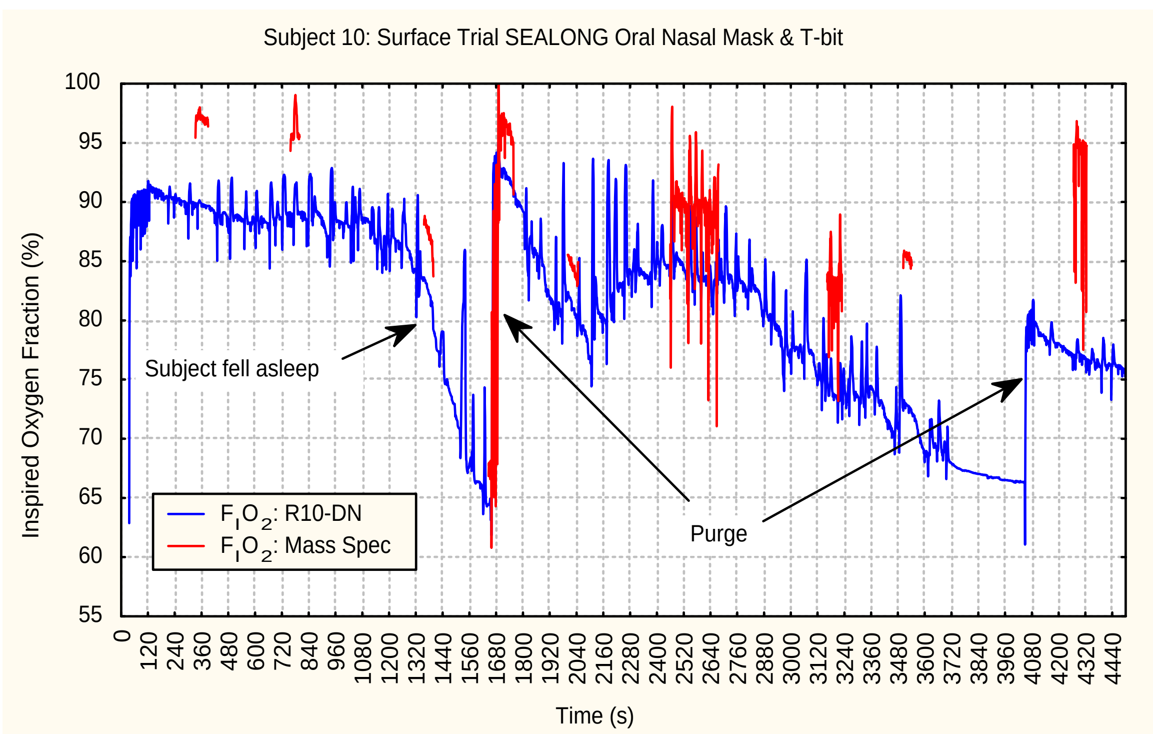

Subject 8: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
100
95
90
85
80
75
70
65
60
55
50
0
120
240
360
480
600
720
840
960
1080
1200
1320
1440
1560
1680
1800
1920
2040
2160
2280
2400
2520
2640
2760
2880
3000
3120
3240
3360
3480
3600
3720
3840
3960
4080
4200
4320
4440
Time (s)
Purge
Leaks shown on mass spec trace likely due to poor O-ring seal for CO 2 canister lid
F I O 2: R10-DN
F I O 2: Mass Spec

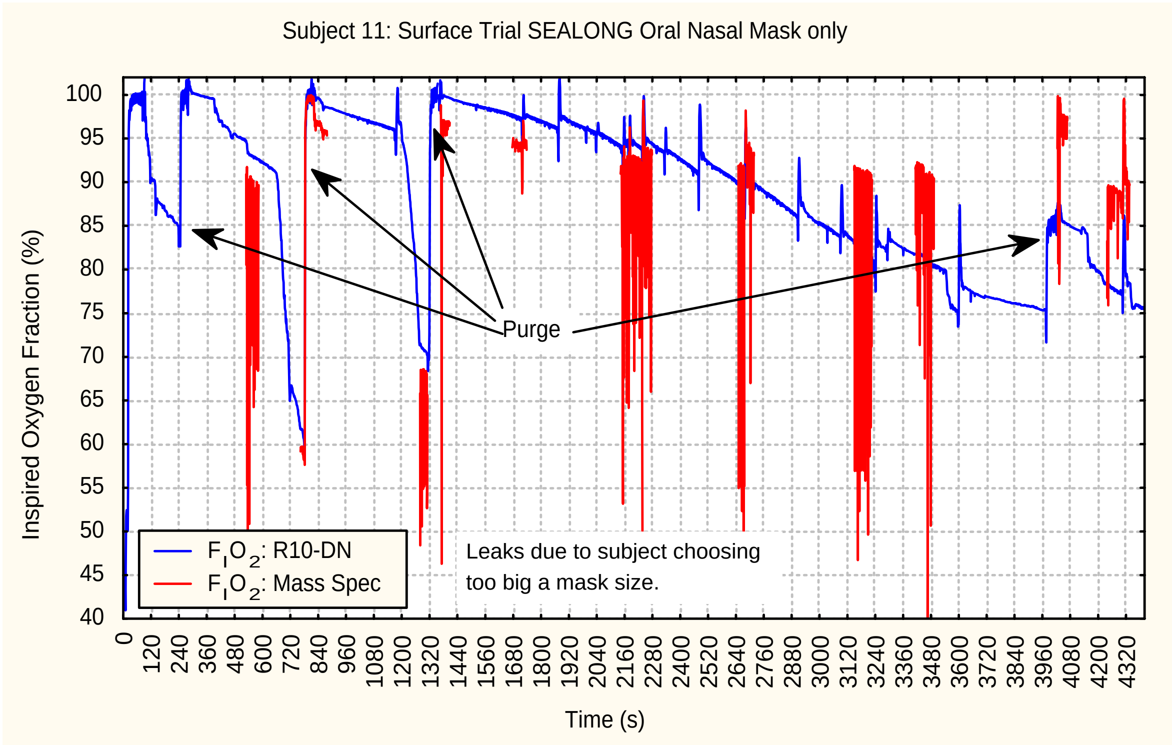

Subject 8: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
100
95
90
85
80
75
70
65
60
55
50
45
40
35
30
25
0
120
240
360
480
600
720
840
960
1080
1200
1320
1440
1560
1680
1800
1920
2040
2160
2280
2400
2520
2640
2760
2880
3000
3120
3240
3360
3480
3600
3720
3840
3960
4080
4200
4320
4440
Time (s)
Purge
Evidence of leaks on inspiration: may be due to poor CO 2 canister lid O-ring seal
F I O 2: R10-DN
F I O 2: Mass Spec


Subject 9: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Mask fell off face
Purge
Subject reports small mask leak over bridge of nose
F_IO_2: R10-DN
F_IO_2: Mass Spec

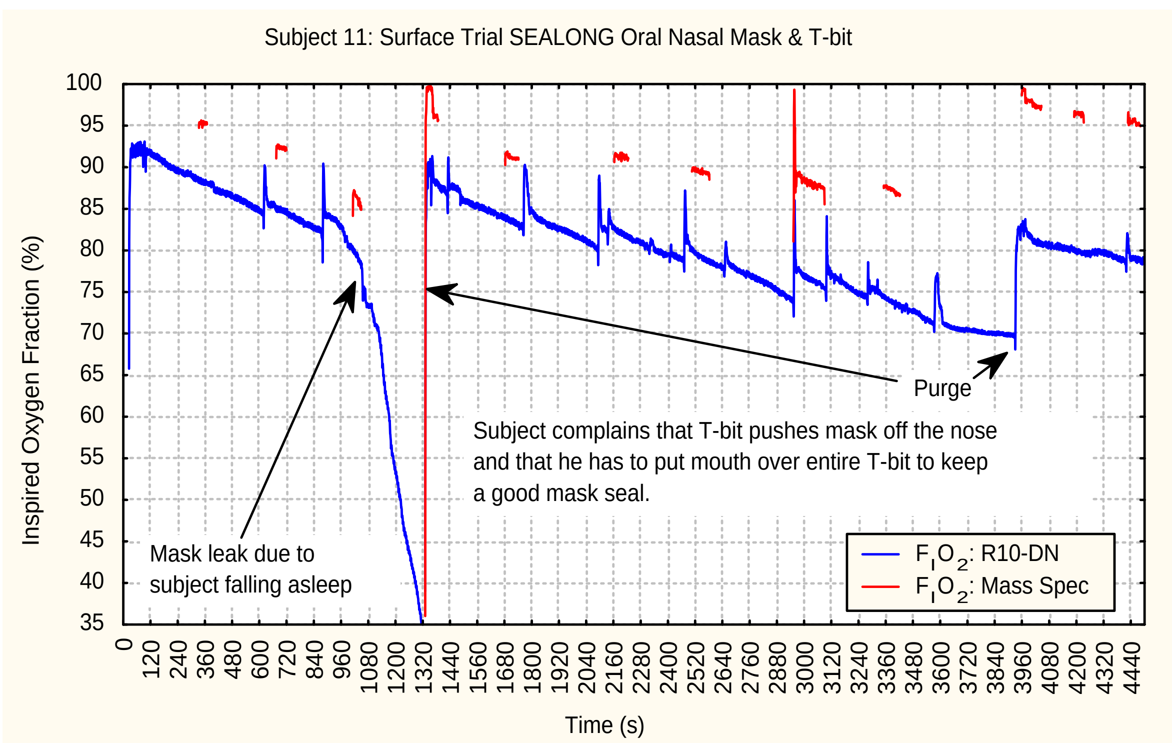

Subject 9: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
Leaks due to T-bit insert preventing a good mask seal over the bridge of the nose. Also mask too large
F_IO_2: R10-DN
F_IO_2: Mass Spec


Subject 10: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Mask fell off
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec

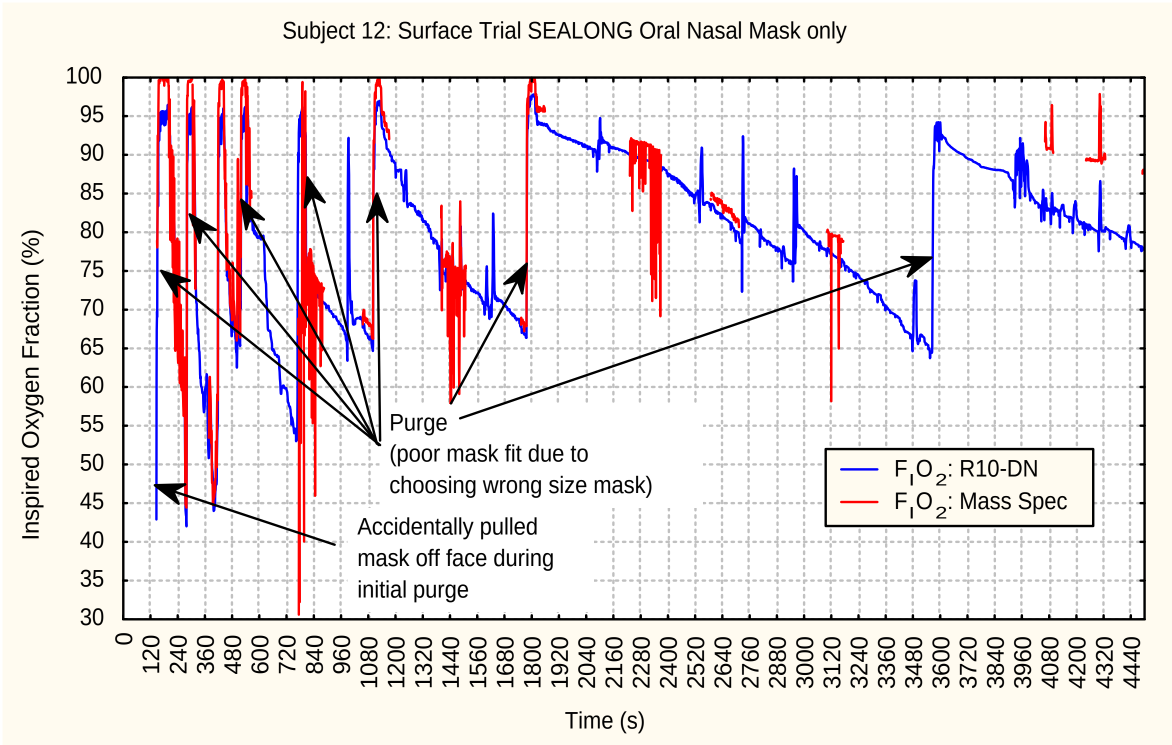

Subject 10: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
Time (s)
Subject fell asleep
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec



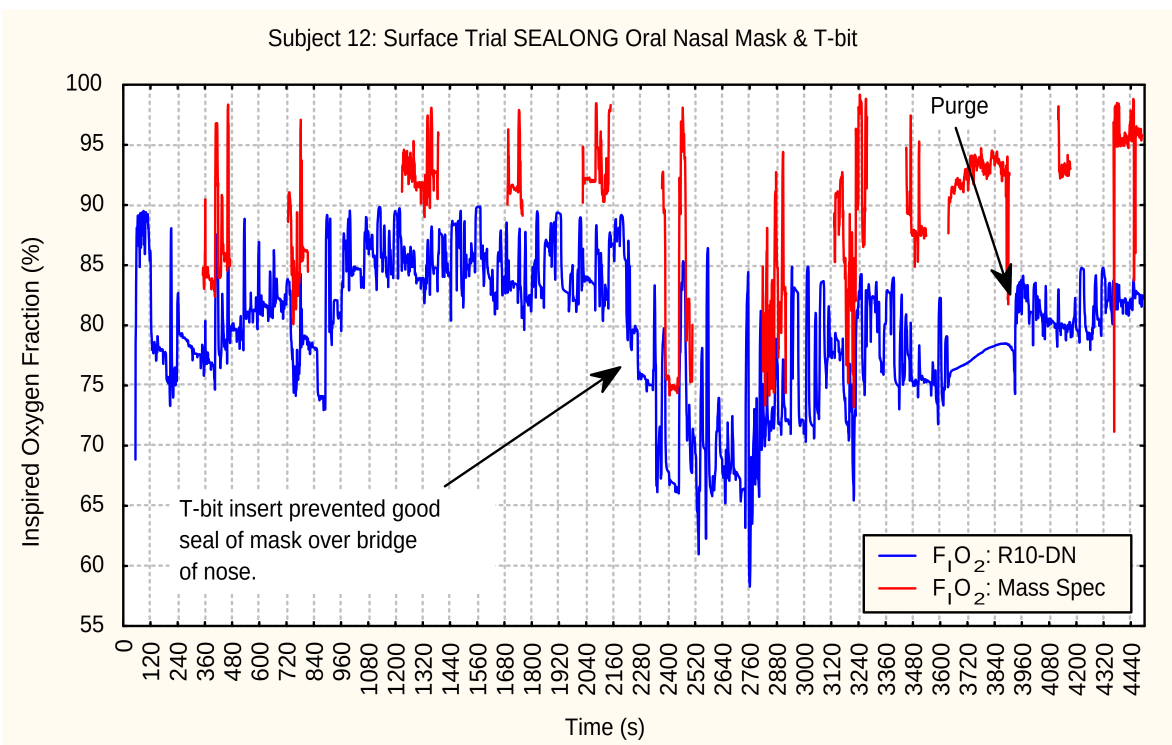
Subject 11: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Purge
Leaks due to subject choosing
too big a mask size.
F_IO_2: R10-DN
F_IO_2: Mass Spec



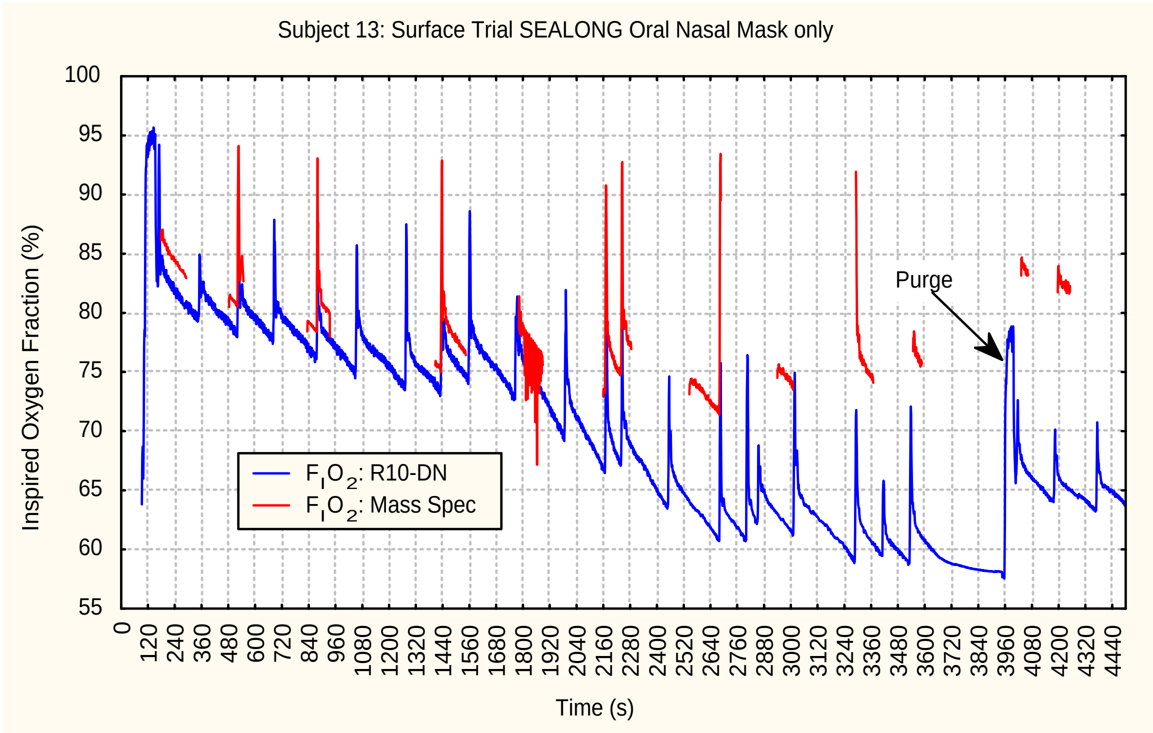
Subject 11: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
Subject complains that T-bit pushes mask off the nose
and that he has to put mouth over entire T-bit to keep
a good mask seal.
Mask leak due to
subject falling asleep
F_IO_2: R10-DN
F_IO_2: Mass Spec



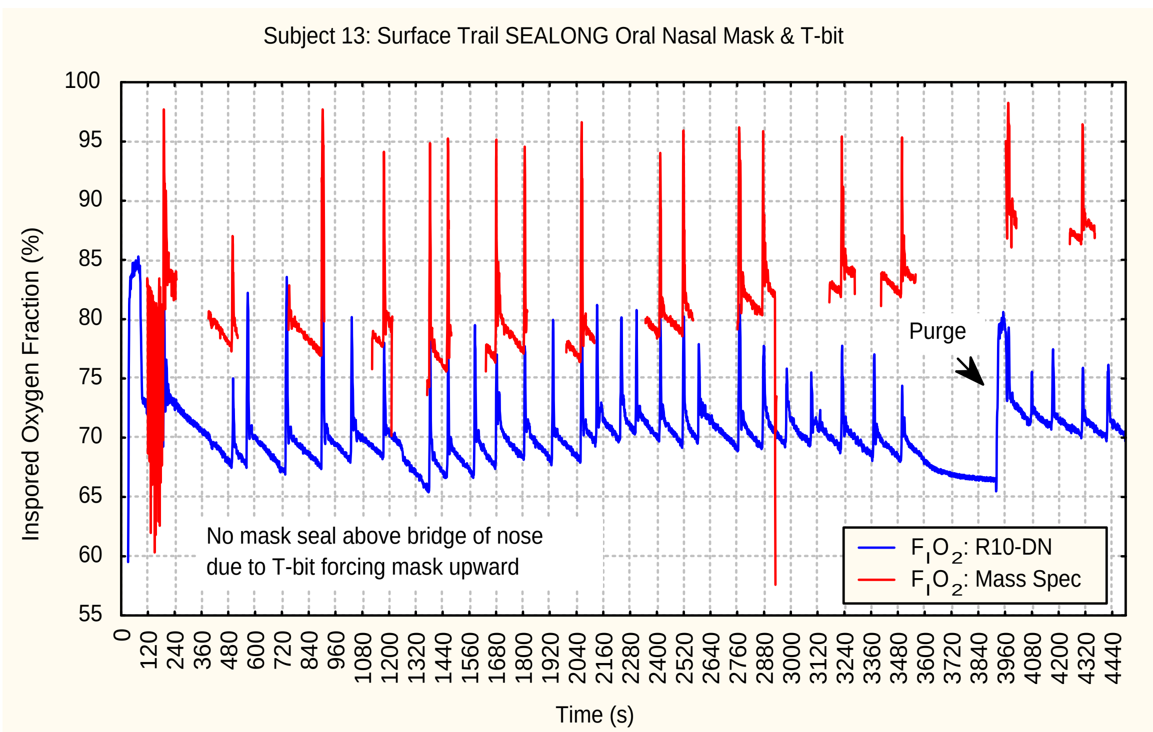
Subject 12: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Purge
(poor mask fit due to
choosing wrong size mask)
Accidentally pulled
mask off face during
initial purge
F_IO_2: R10-DN
F_IO_2: Mass Spec



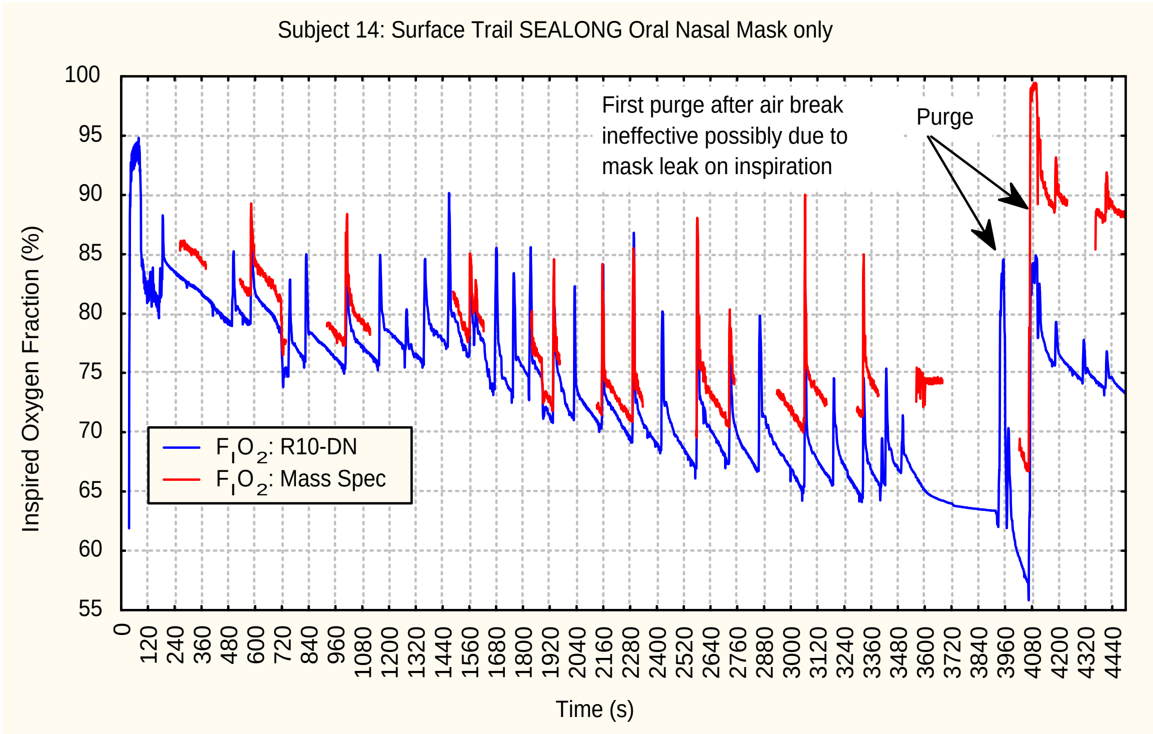
Subject 12: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
T-bit insert prevented good
seal of mask over bridge
of nose.
F_IO_2: R10-DN
F_IO_2: Mass Spec

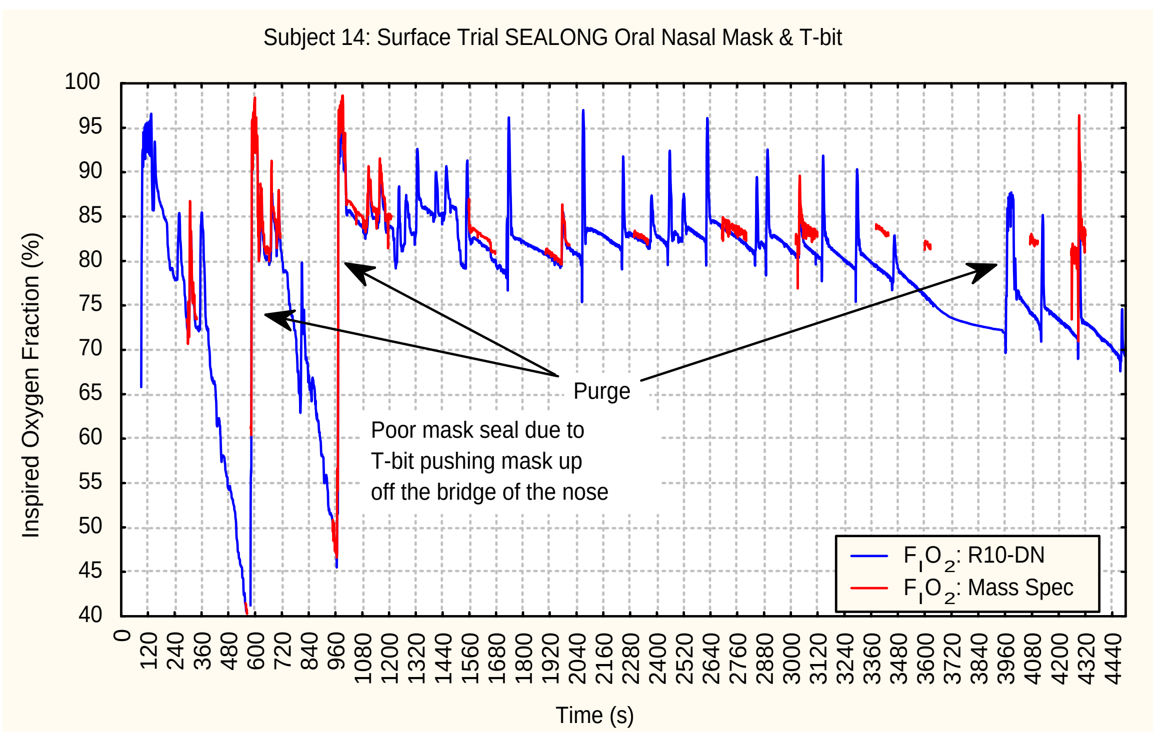


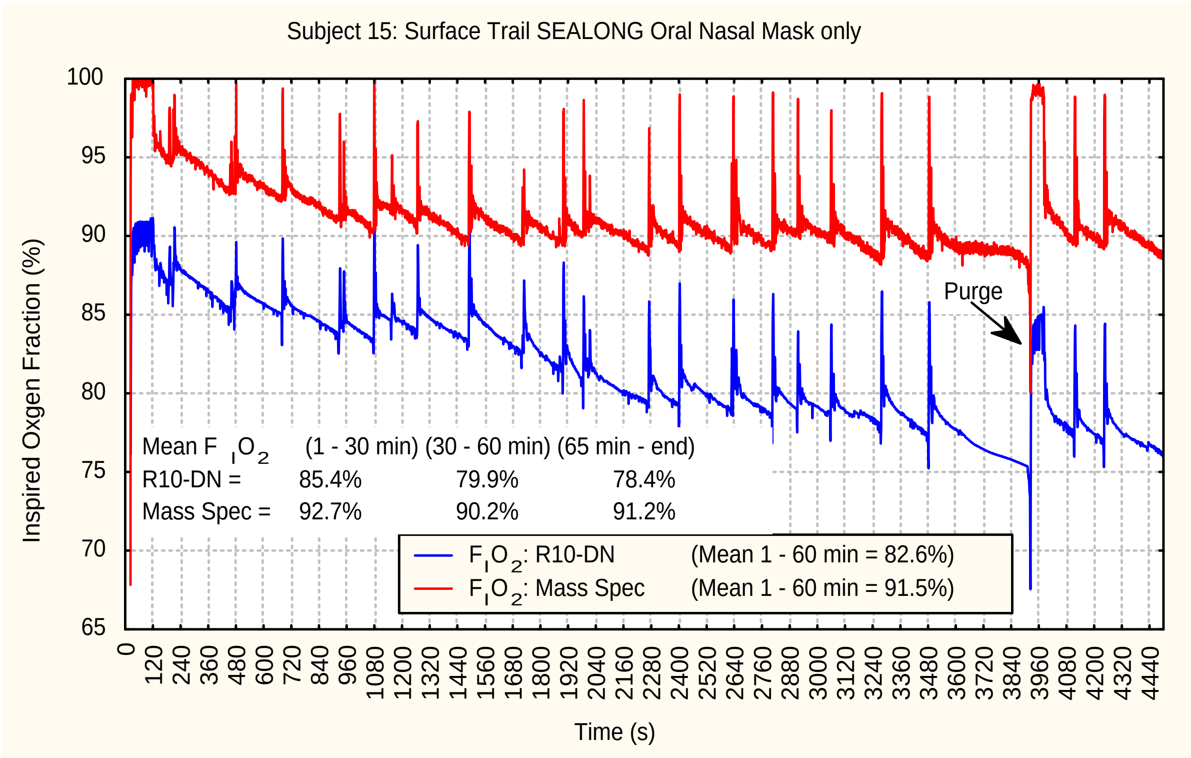
Subject 13: Surface Trial SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec

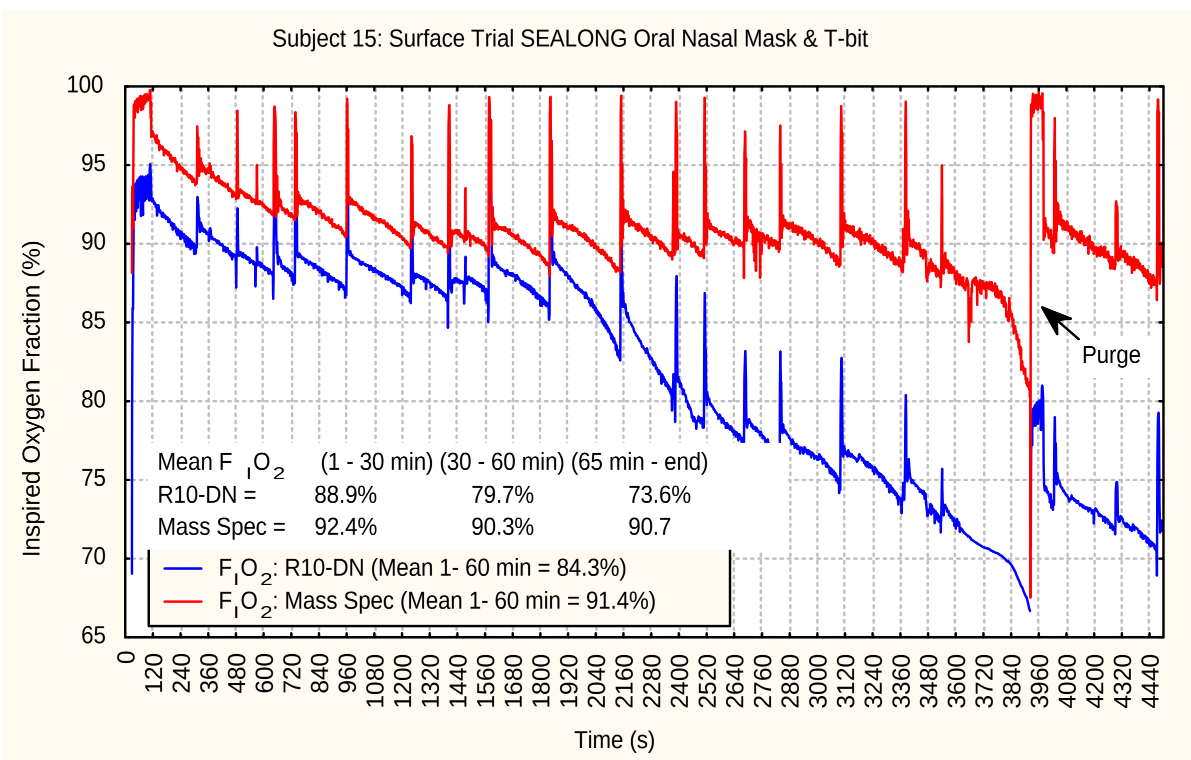


Subject 13: Surface Trail SEALONG Oral Nasal Mask & T-bit
Inspored Oxygen Fraction (%)
Time (s)
Purge
No mask seal above bridge of nose
due to T-bit forcing mask upward
F_IO_2: R10-DN
F_IO_2: Mass Spec


Subject 14: Surface Trail SEALONG Oral Nasal Mask only
Inspired Oxygen Fraction (%)
Time (s)
First purge after air break
ineffective possibly due to
mask leak on inspiration
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec


Subject 14: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxygen Fraction (%)
Time (s)
Purge
Poor mask seal due to
T-bit pushing mask up
off the bridge of the nose
F_IO_2: R10-DN
F_IO_2: Mass Spec


Subject 15: Surface Trail SEALONG Oral Nasal Mask only
Inspired Oxgen Fraction (%)
Time (s)
Purge
Mean F_IO_2 (1 - 30 min) (30 - 60 min) (65 min - end)
R10-DN = 85.4% 79.9% 78.4%
Mass Spec = 92.7% 90.2% 91.2%
F_IO_2: R10-DN (Mean 1 - 60 min = 82.6%)
F_IO_2: Mass Spec (Mean 1 - 60 min = 91.5%)


Subject 15: Surface Trial SEALONG Oral Nasal Mask & T-bit
Inspired Oxgen Fraction (%)
Time (s)
Purge
Mean F_IO_2 (1 - 30 min) (30 - 60 min) (65 min - end)
R10-DN = 88.9% 79.7% 73.6%
Mass Spec = 92.4% 90.3% 90.7
F_IO_2: R10-DN (Mean 1- 60 min = 84.3%)
F_IO_2: Mass Spec (Mean 1- 60 min = 91.4%)

Appendix B

Individual Subject Data for the 60 fsw Trials

The data shown in Tables B1 and B2 summarize the individual subject data shown in the following plots of F_IO_2 and oxygen consumption versus time for the two 20 minute O_2 breathing periods at 60 fsw. Subjects used the modified MBS 2000 with the SEALONG Oral nasal mask plus T-bit. The individual subject plots that follow Tables B1 and B2 were generated by resampling the raw BIOPAC data files (original sample rate = 50 Hz) at a 1 Hz sample rate and then importing the resampled data into Statistica (Statsoft™ Tulsa, OK) software for plotting. The F_IO_2 data measured using the Mass spec and O_2 analyzer have been time aligned with the R10-DN F_IO_2 measurements to account for gas sample line delays. Subjects who participated in the surface trials retained their original subject number identifier. All subjects were US Navy trained divers. Note that the initial purge was a 10-breath purge, and that all subsequent purges were 5 breath purges (see methods section). All volumes are given in standard liters at 1 ATA and 25 °C. Specific notes on the individual data (i.e. reasons for sudden drops in F_IO_2) are given in the appropriate individual graphs.

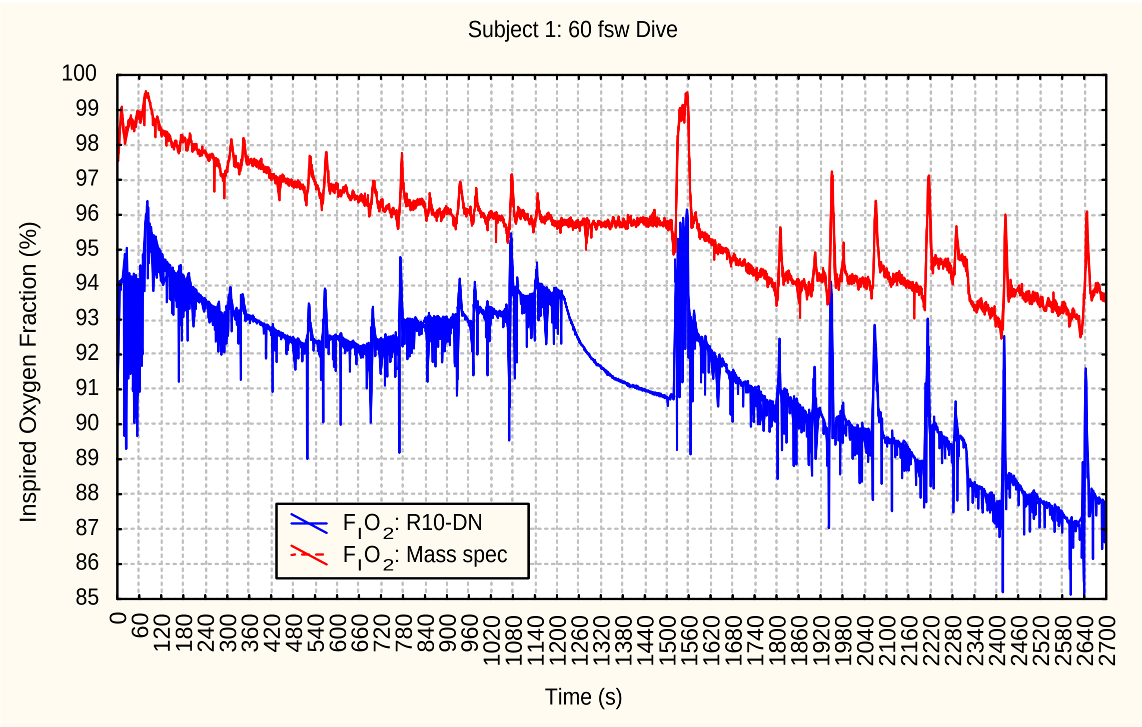
Table B1. Individual subject data for the first 20 min O_2 period at 60 fsw using the modified MBS 2000 with SEALONG Oral nasal mask plus T-bit.

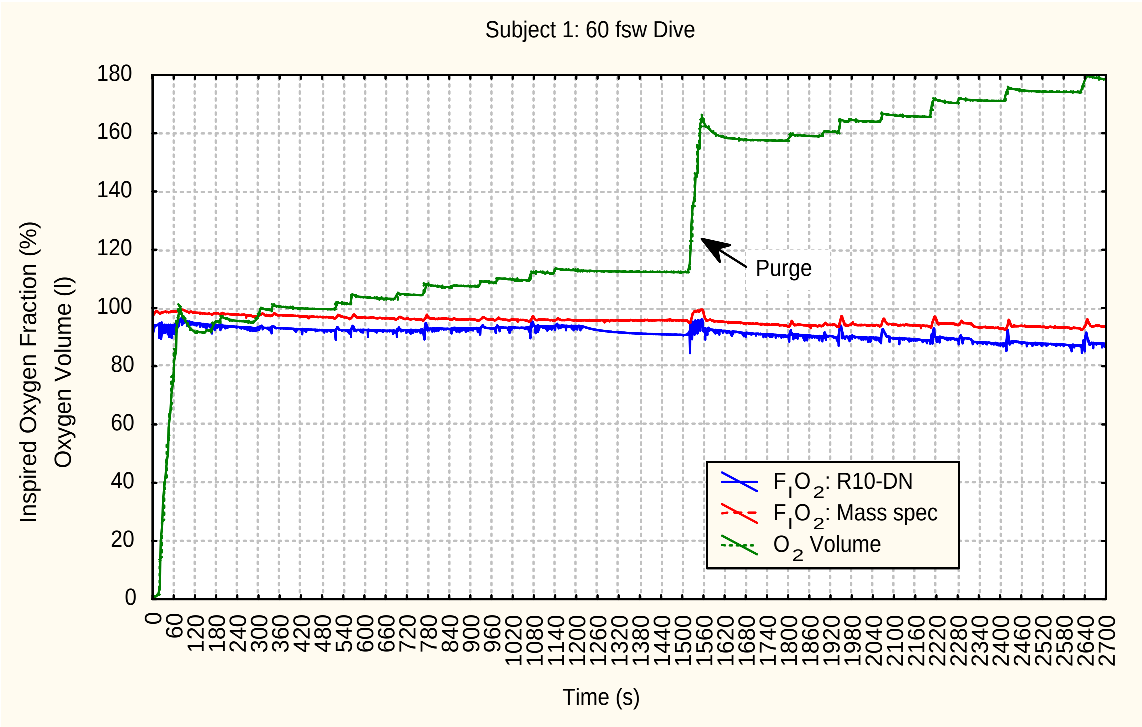
Subject #	10 breath purge Volume (l)	Initial F_IO_2 (after 30 s of rebreathing (%)	Total O_2 consumption over 20 min (l)	Mean dry F_IO_2 over 20 min[1] (%)	Mean F_IO_2 over 20 min R10-DN[2] (%)	# Additional Purges over 20 min
1	90.2	98.5	110.7	96.8[a]	93.0	0
2	94.9	99.3	96.6	94.0[a]	84.0	0
3	78.7	98.8	138.8	91.5[b]	See graph	1
8	95.9	98.9	106.1	95.7[b]	98.0	0
9	83.9	97.8	153.9	91.2[b]	92.0	2
10	72.3	98.5	80.1	93.9[a]	See graph	0
11	74.9	97.0	113.9	91.6[b]	91.0	1
15	61.1	97.2	68.3	95.5[a]	86.0	0
16	68.3	97.1	85.0	94.6[a]	91.0	0
17	118.1	94.9	195.7	90.4[a]	88.0	1
18	56.3	98.2	64.1	92.5[b]	77.0	0
Mean	81.5	97.8	110.2	93.4	88.9	0. 5
SD	17.9	1.2	39.6	2.1	6.1	0.7

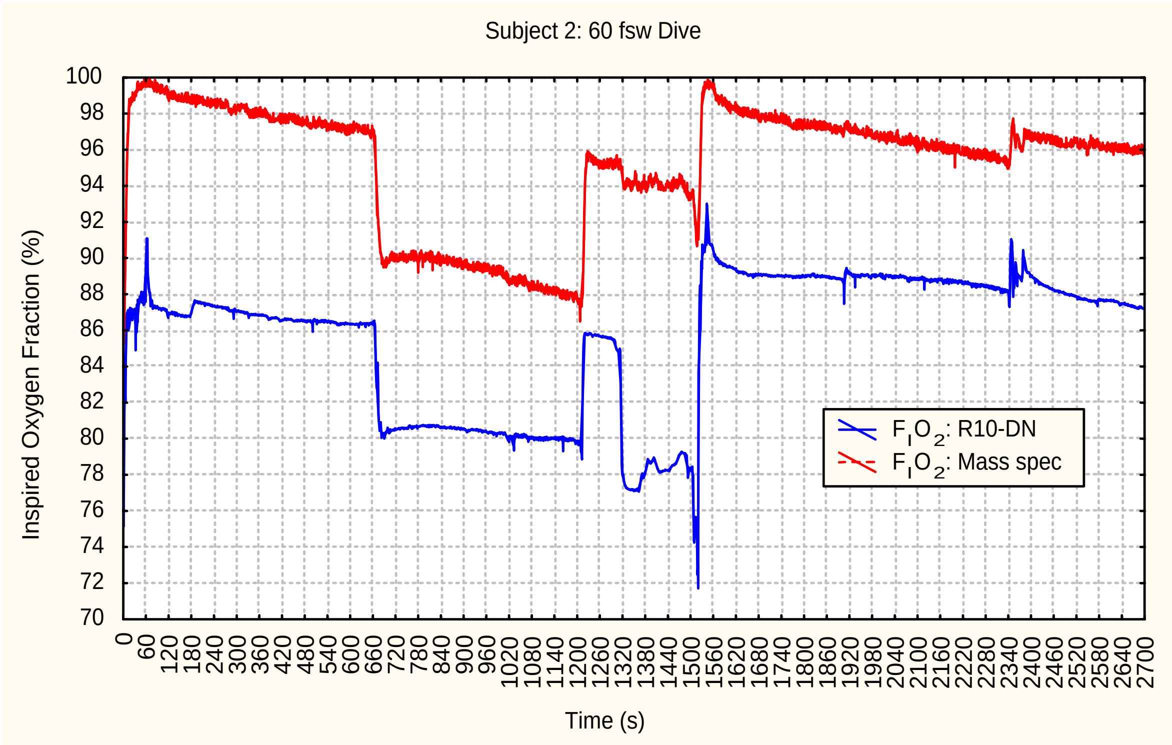
Table B2. Individual subject data for the second 20 min O_2 period at 60 fsw using the modified MBS 2000 with SEALONG Oral nasal mask plus T-bit.

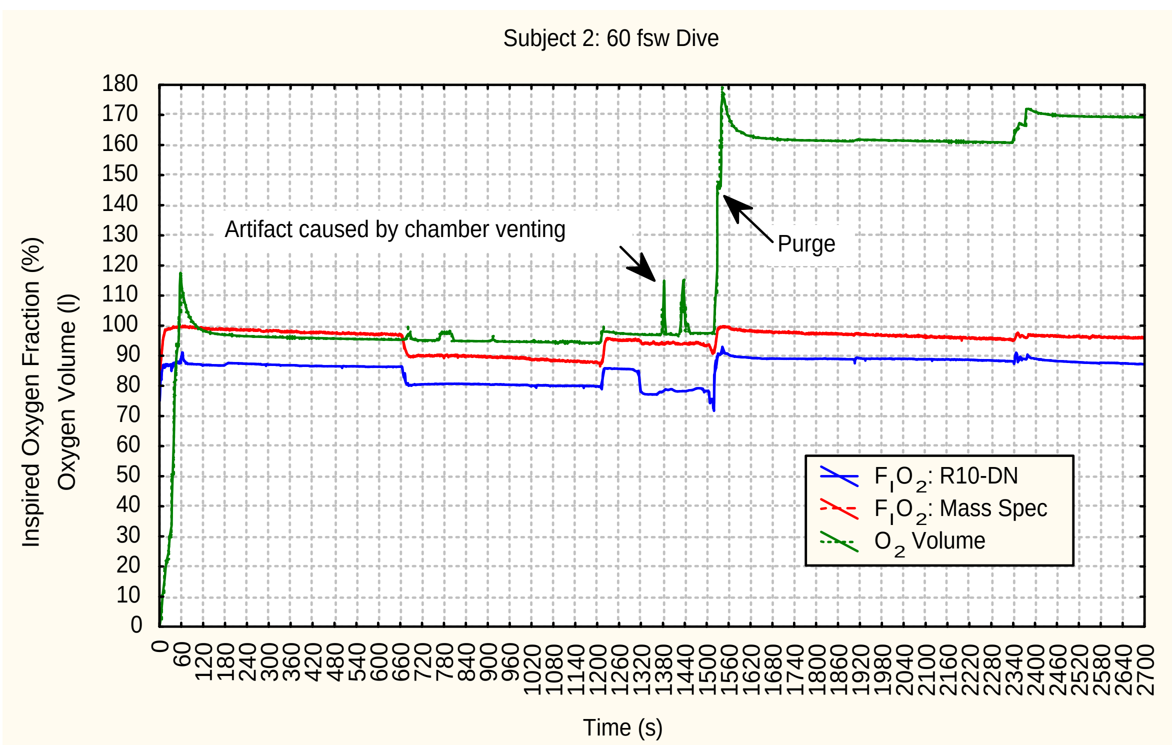
Subject #	5 breath purge Volume (l)	Initial F_IO_2 (after 30 s of rebreathing (%)	Total O_2 consumption over 20 min (l)	Mean dry F_IO_2 over 20 min[1] (%)	Mean F_IO_2 over 20 min R10-DN[2] (%)	# Additional Purges over 20 min
1	47.4	95.8	64.9	94.2[a]	90.0	0
2	64.1	98.5	70.6	96.8[a]	89.0	0
3	38.6	94.5	61.4	93.2[b]	See graph	0
8	44.7	96.3	58.8	94.7[b]	99.8	0
9	42.0	97.3	88.4	89.8[b]	94.0	1
10	42.8	97.4	55.2	93.5[a]	See graph	0
11	53.6	97.6	68.9	87.7[a]	91.0	0
15	31.8	92.4	40.7	91.3[b]	85.0	0
16	38.2	94.1	53.8	94.1[a]	93.0	0
17	55.5	91.0	76.3	88.7[a]	89.0	1
18	34.4	97.2	44.1	93.7[b]	80.0	0
Mean	44.8	95.6	62.1	92.5	90.1	0.2
SD	9.7	2.4	13.9	2.8	5.6	0.4

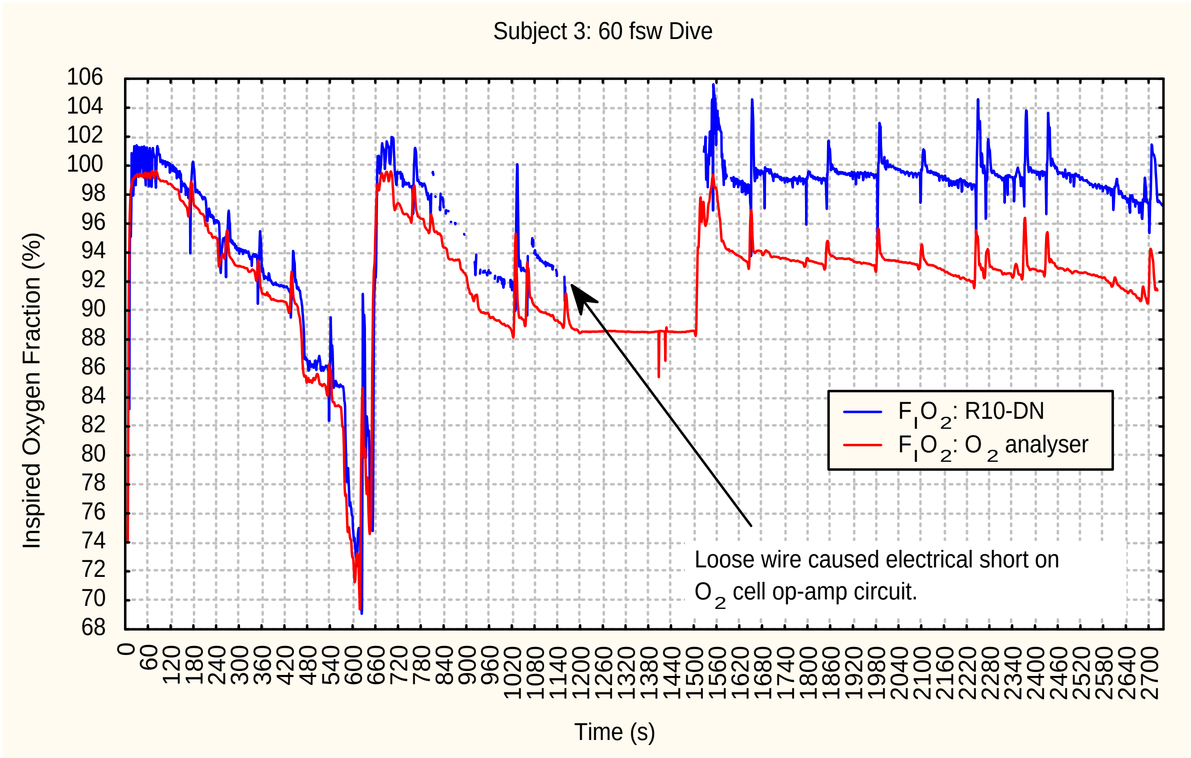
[1] F_IO_2 measurements taken with the Mass Spectrometer[a] and S-3A oxygen analyzer[b] are dry fractions.
[2] F_IO_2 measurements taken with the R10-DN oxygen cell are wet fractions (i.e. are not adjusted for water vapor pressure).

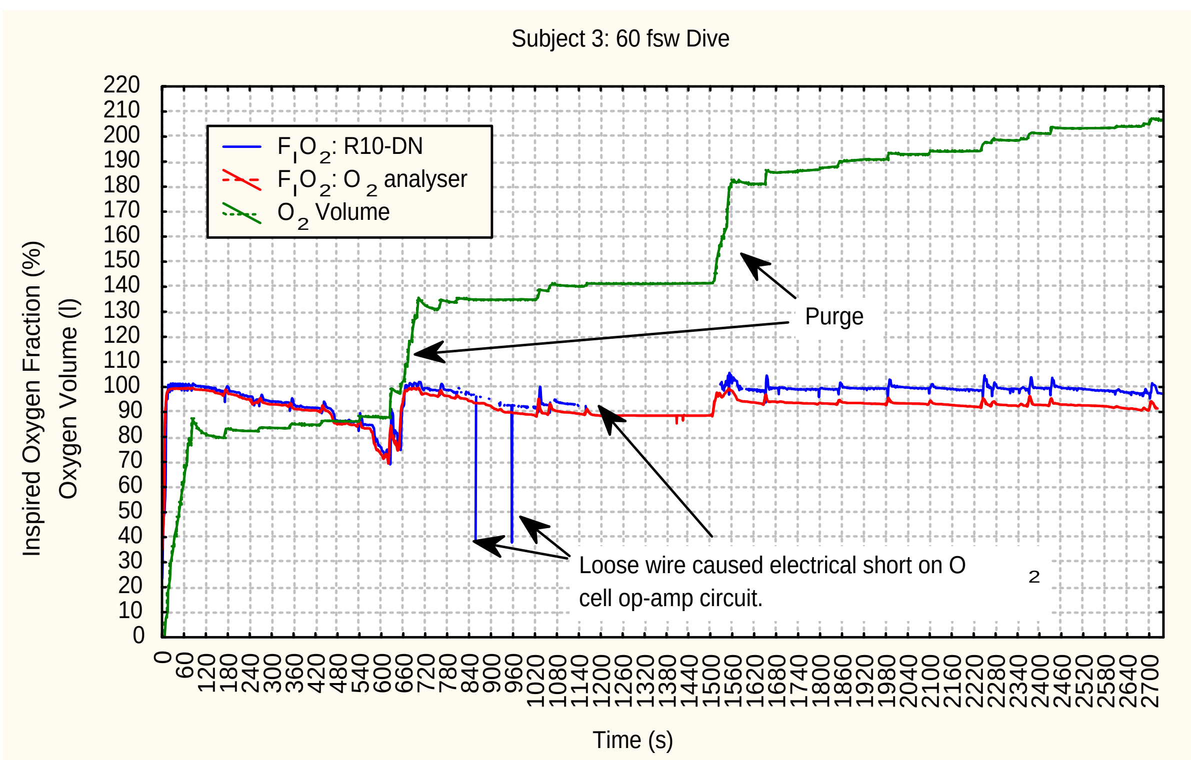

Subject 1: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass spec

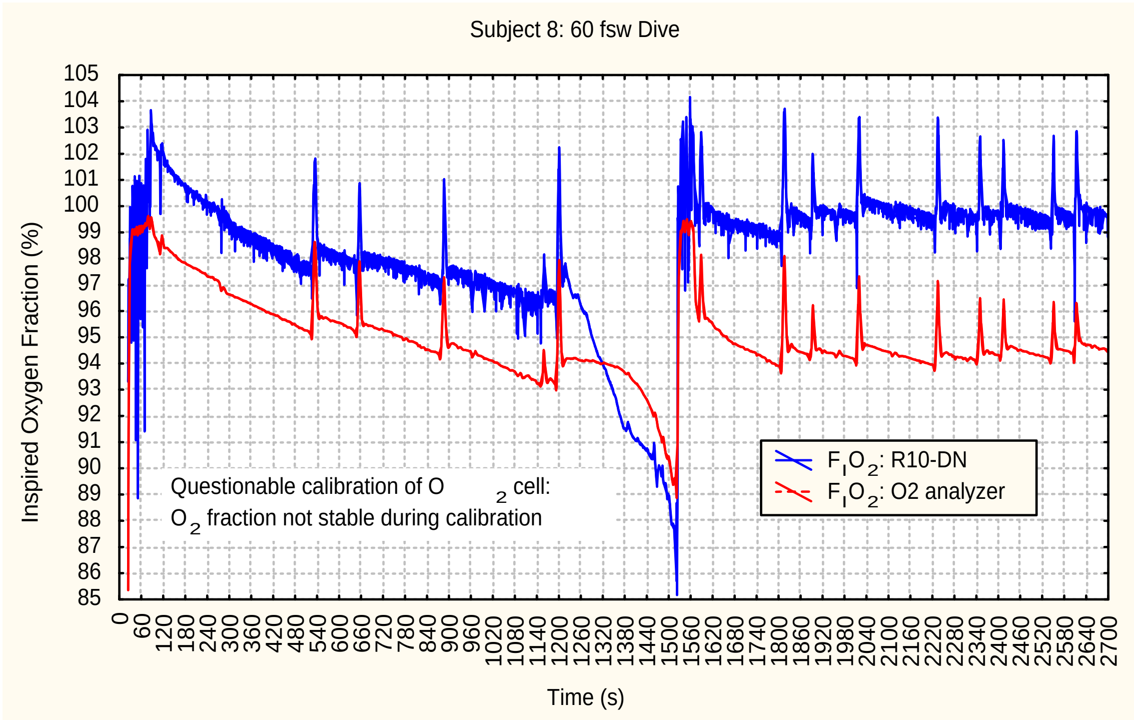

Subject 1: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass spec
O_2 Volume

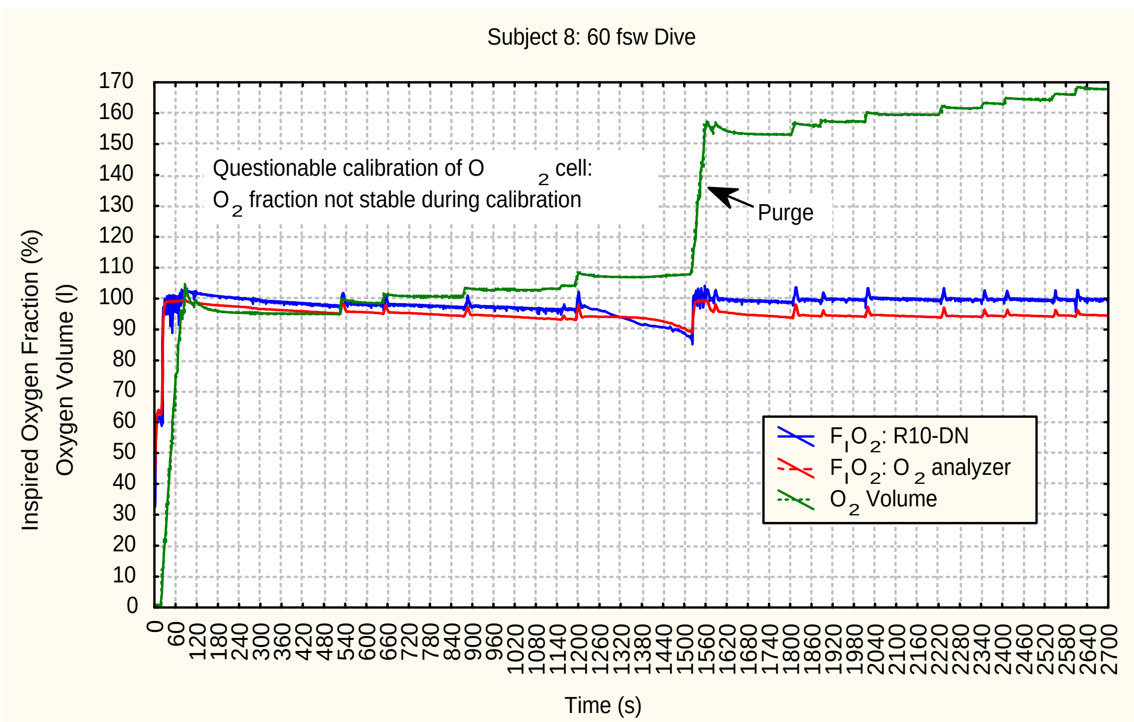

Subject 2: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F$_I$O$_2$: R10-DN
F$_I$O$_2$: Mass spec

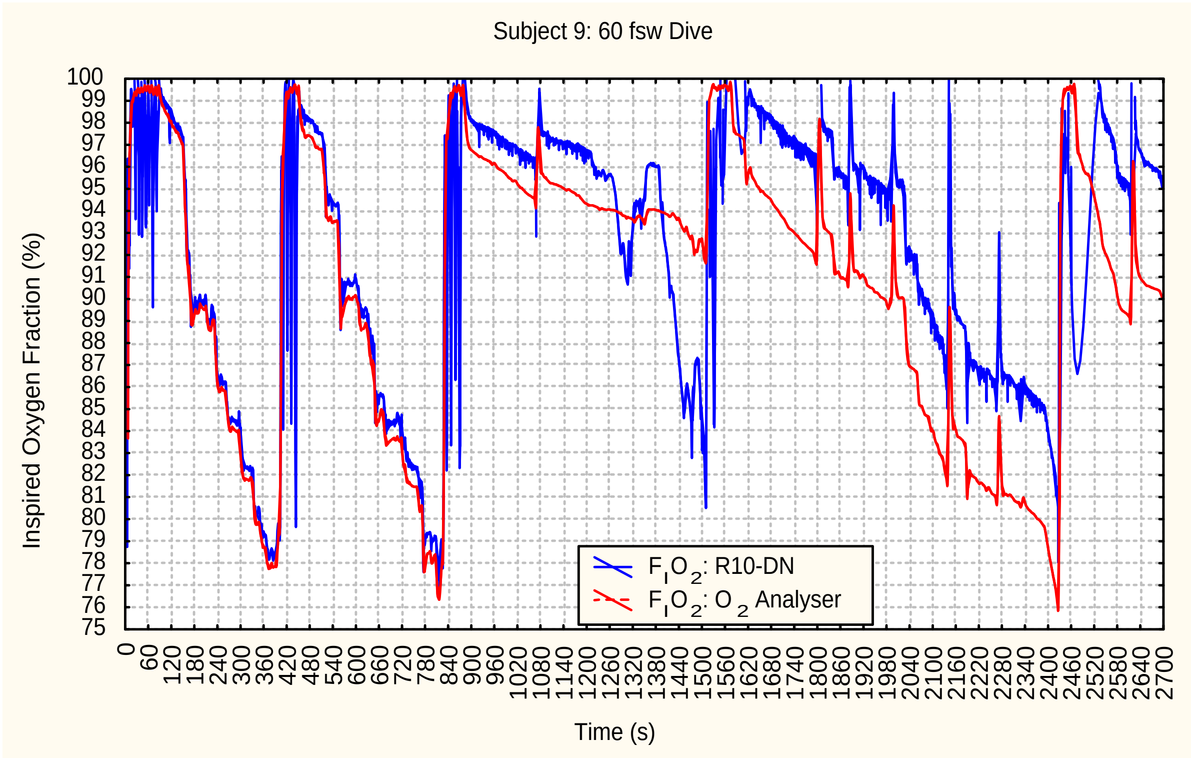

Subject 2: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
Artifact caused by chamber venting
Purge
F$_I$O$_2$: R10-DN
F$_I$O$_2$: Mass Spec
O$_2$ Volume

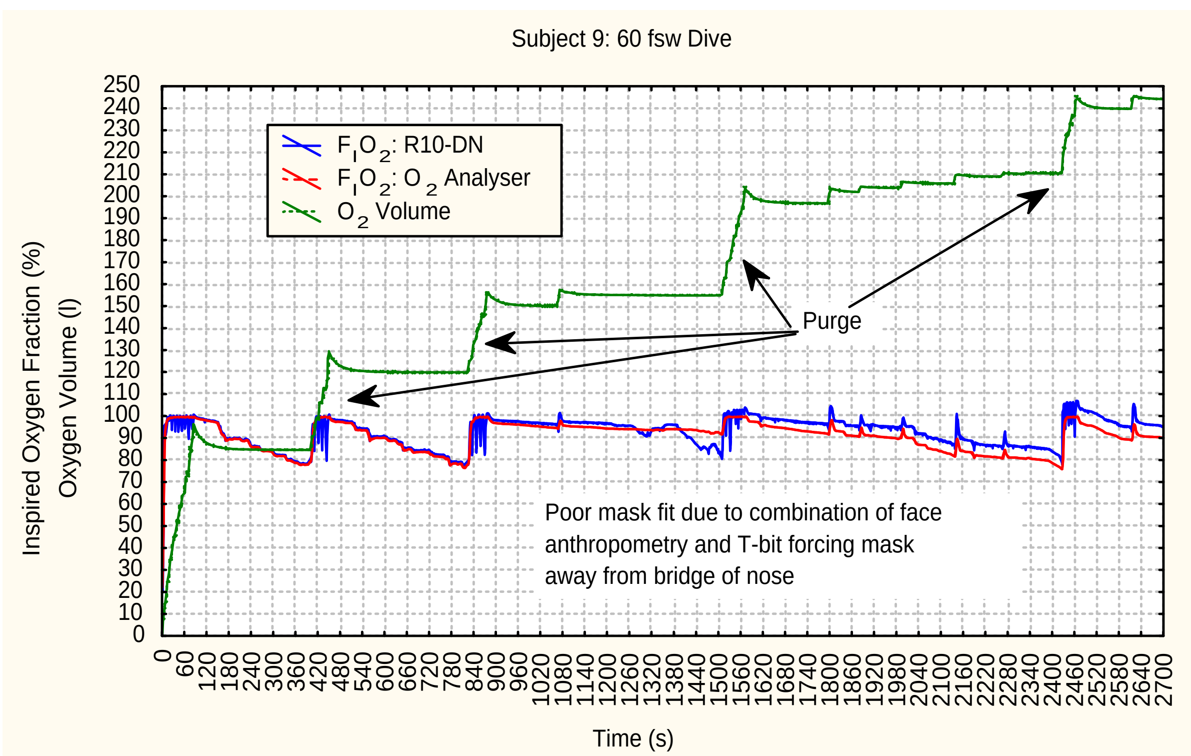

Subject 3: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: O_2 analyser
Loose wire caused electrical short on O_2 cell op-amp circuit.

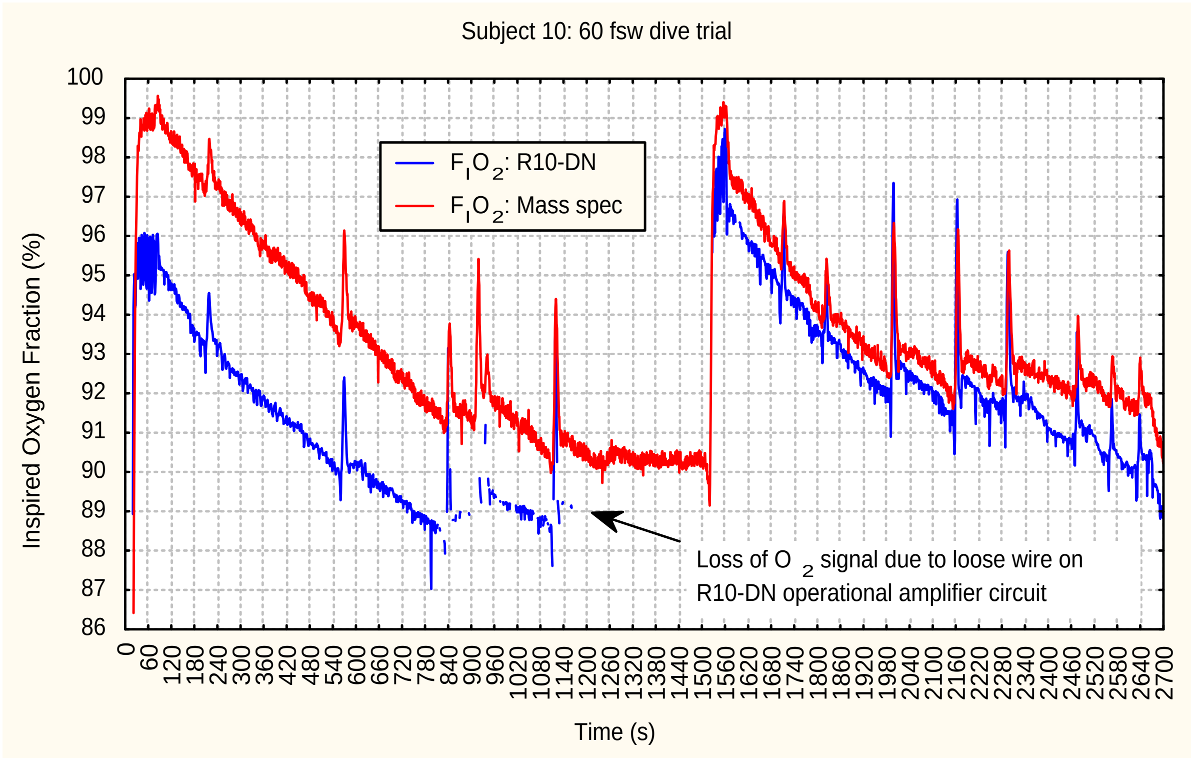

Subject 3: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
F_IO_2: R10-DN
F_IO_2: O_2 analyser
O_2 Volume
Purge
Loose wire caused electrical short on O_2 cell op-amp circuit.

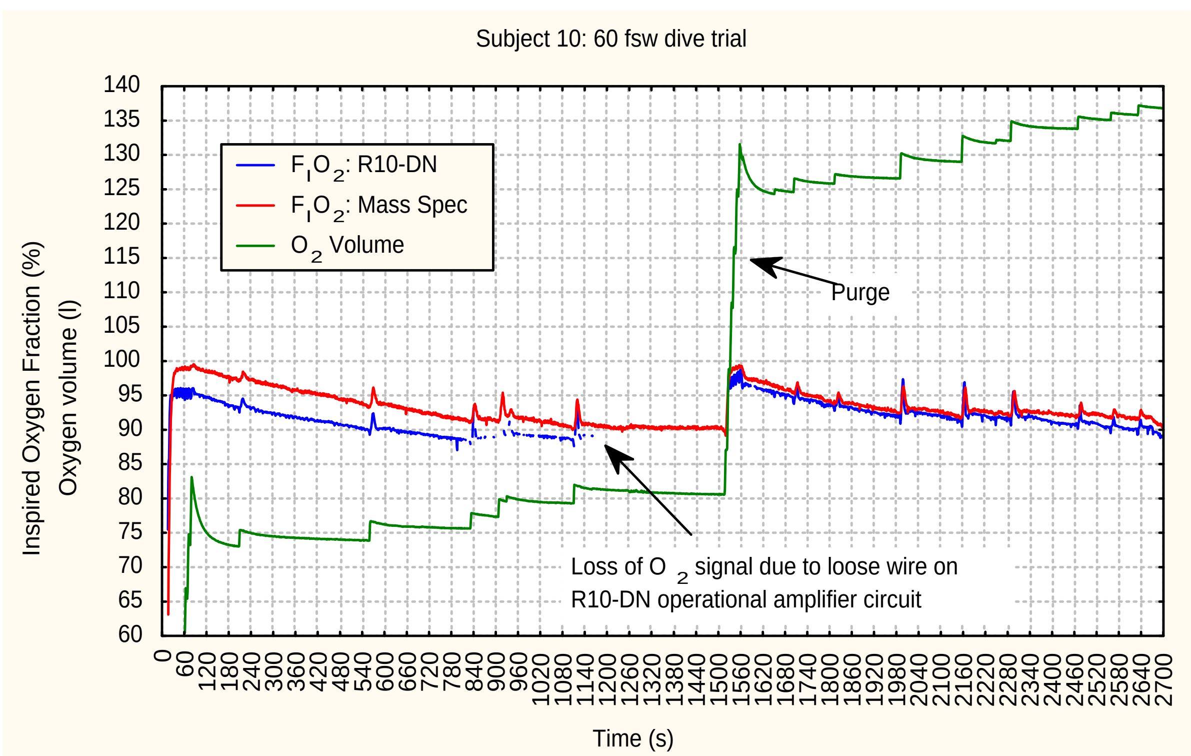

Subject 8: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
Questionable calibration of O 2 cell:
O 2 fraction not stable during calibration
F I O 2: R10-DN
F I O 2: O2 analyzer

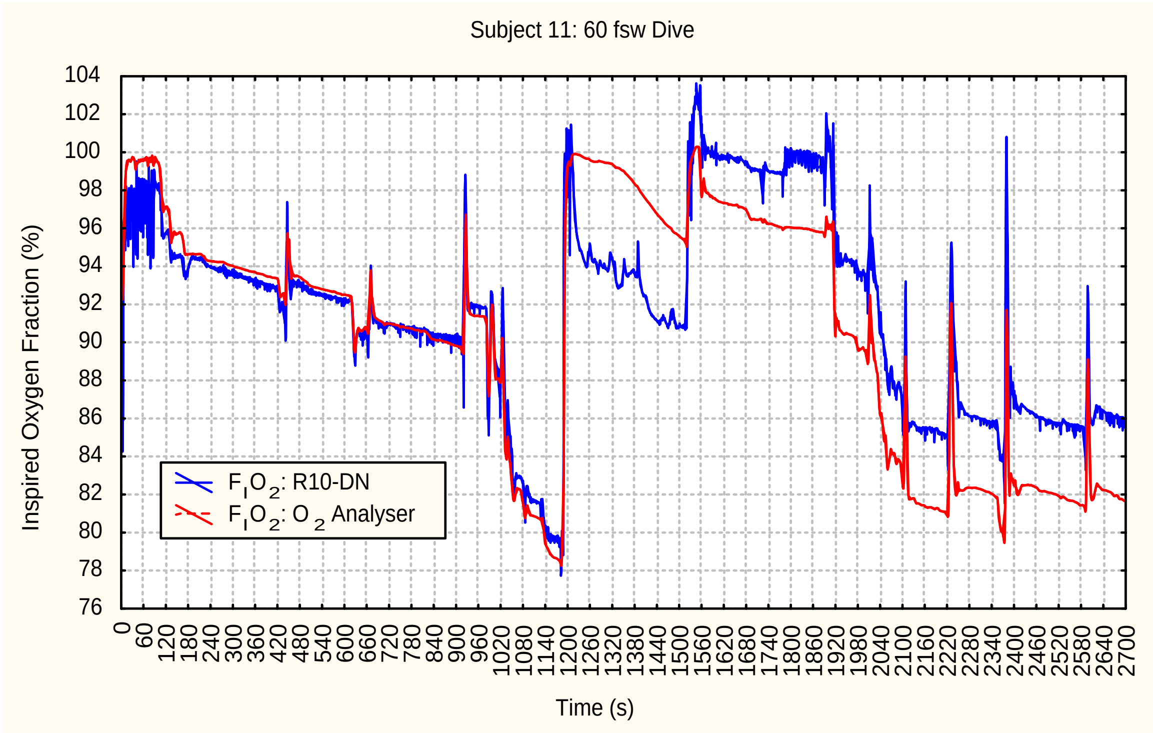

Subject 8: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
Questionable calibration of O 2 cell:
O 2 fraction not stable during calibration
Purge
F I O 2: R10-DN
F I O 2: O 2 analyzer
O 2 Volume

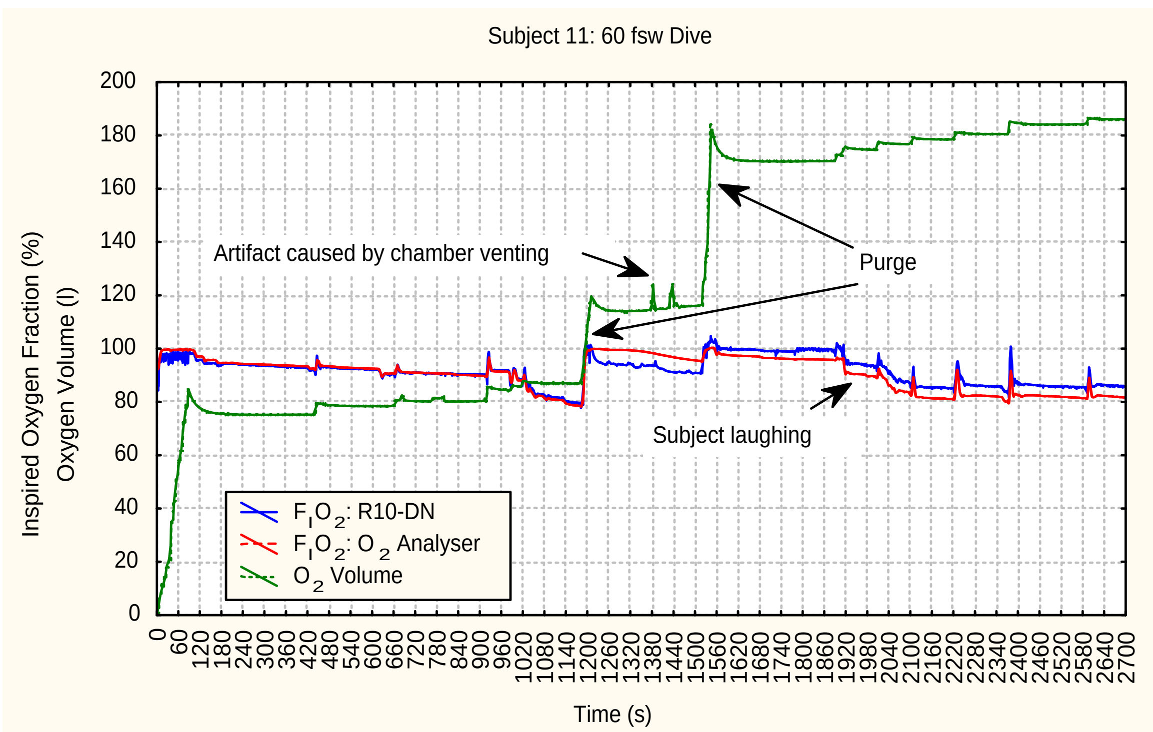

Subject 9: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: O_2 Analyser

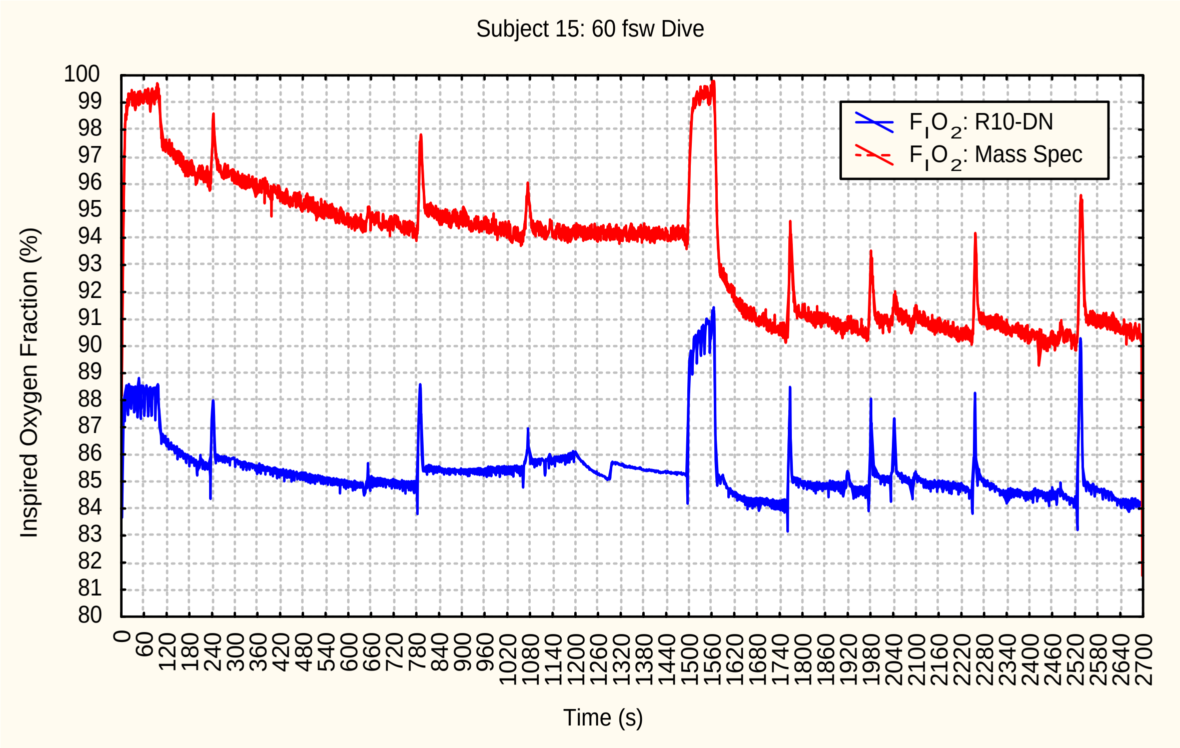

Subject 9: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
F_IO_2: R10-DN
F_IO_2: O_2 Analyser
O_2 Volume
Purge
Poor mask fit due to combination of face
anthropometry and T-bit forcing mask
away from bridge of nose


Subject 10: 60 fsw dive trial
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass spec
Loss of O_2 signal due to loose wire on
R10-DN operational amplifier circuit

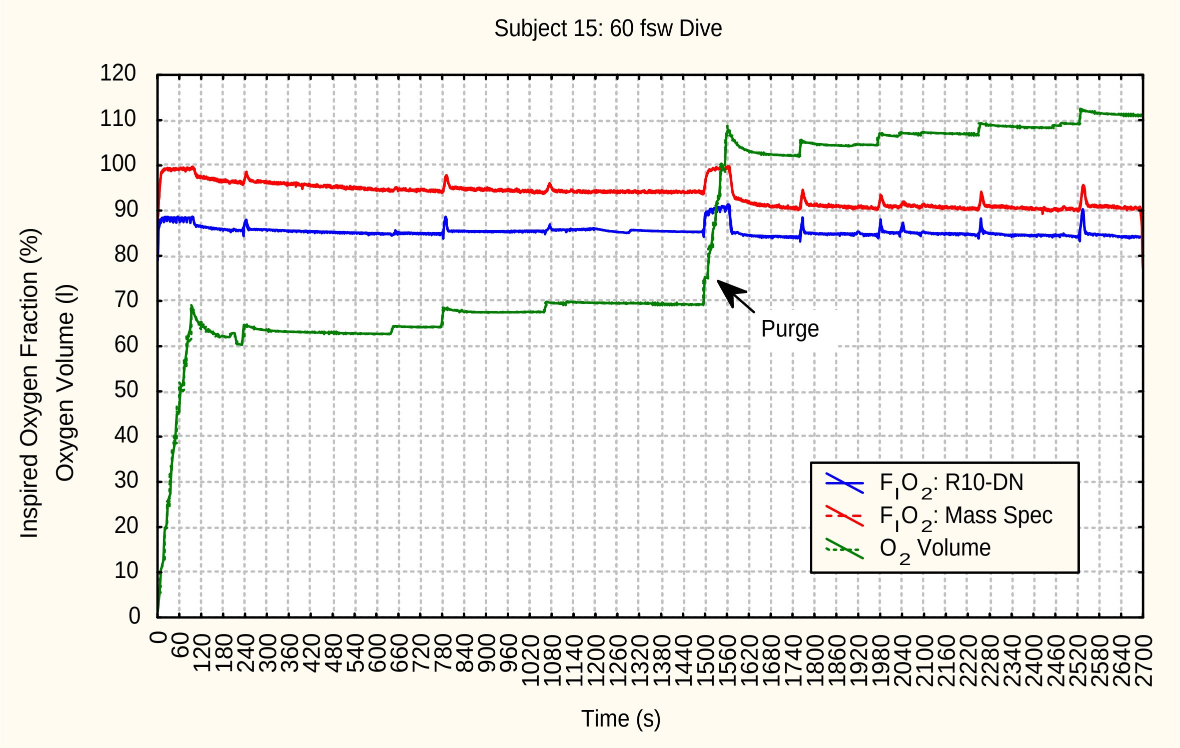

Subject 10: 60 fsw dive trial
Inspired Oxygen Fraction (%)
Oxygen volume (l)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass Spec
O_2 Volume
Purge
Loss of O_2 signal due to loose wire on
R10-DN operational amplifier circuit


Subject 11: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F$_I$O$_2$: R10-DN
F$_I$O$_2$: O$_2$ Analyser

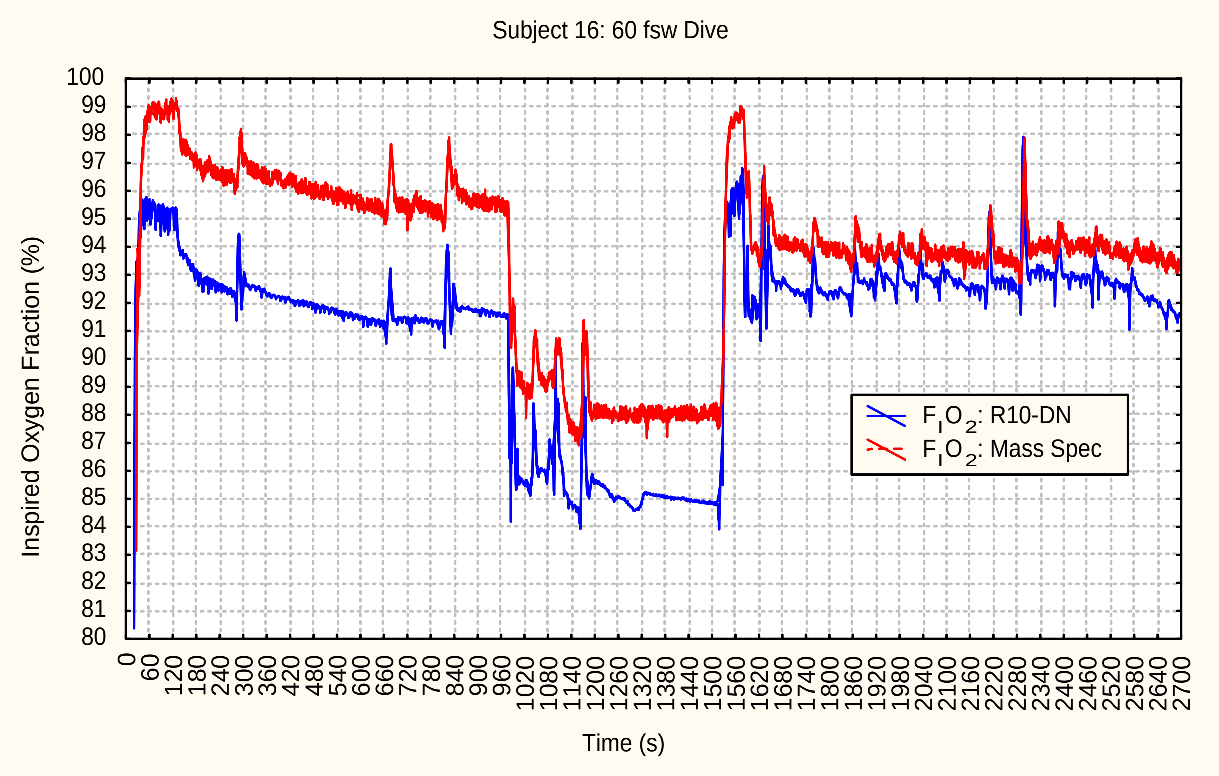

Subject 11: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
Artifact caused by chamber venting
Purge
Subject laughing
F$_I$O$_2$: R10-DN
F$_I$O$_2$: O$_2$ Analyser
O$_2$ Volume

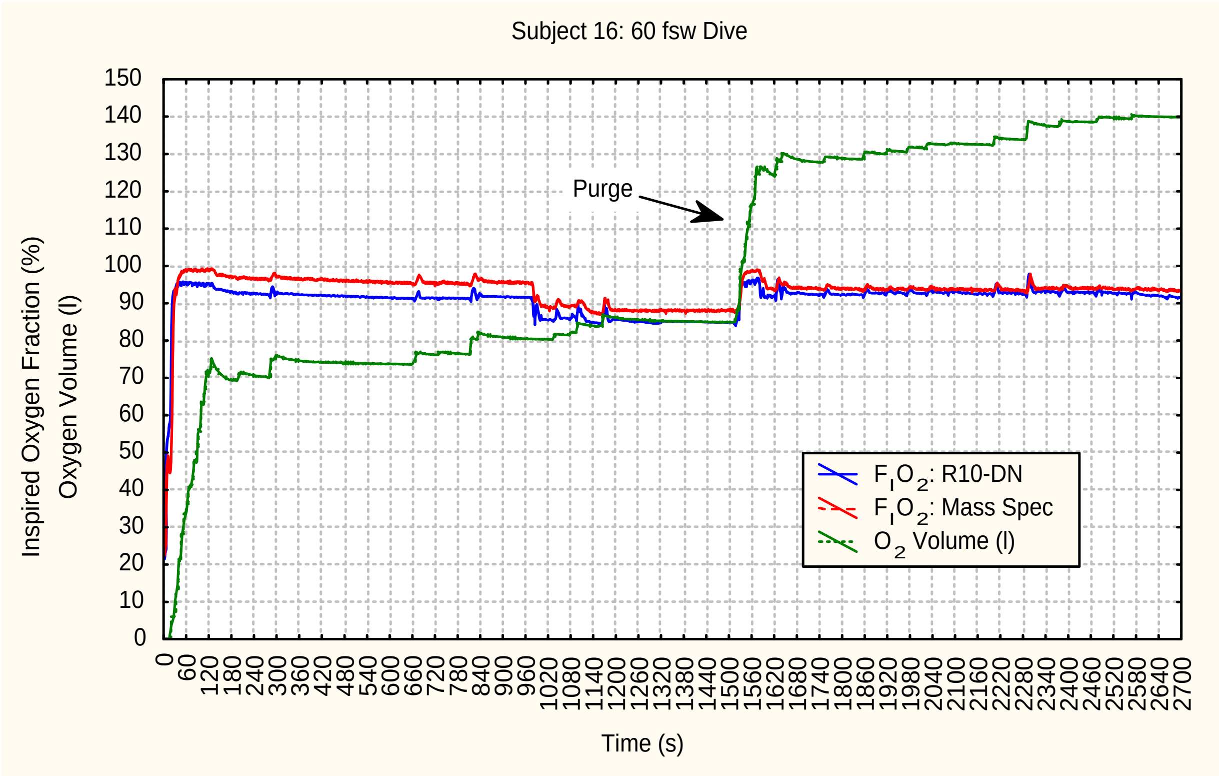


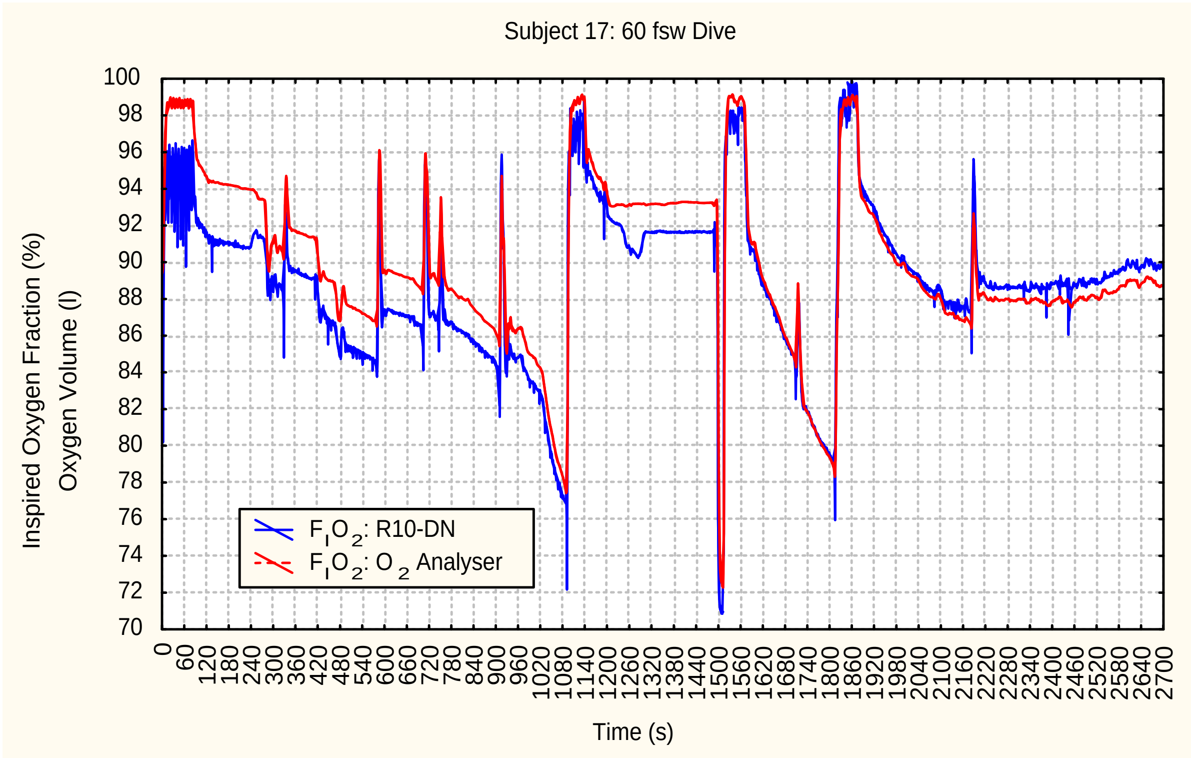
Subject 15: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass Spec

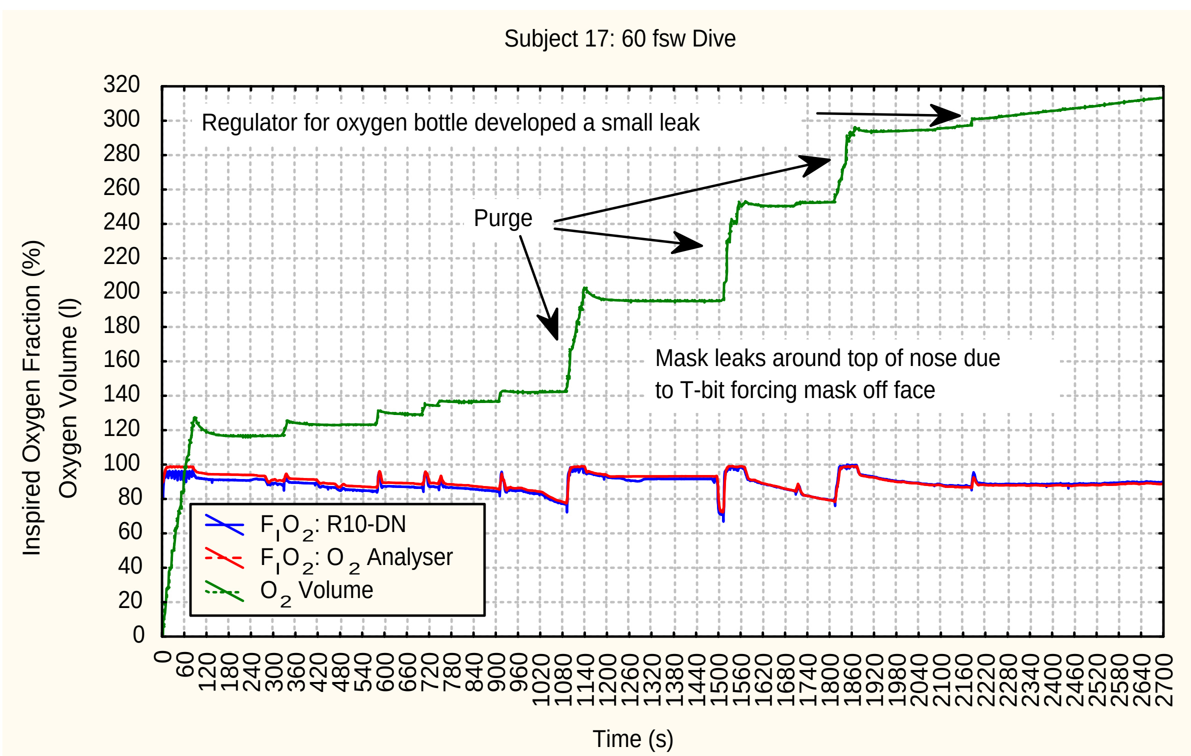


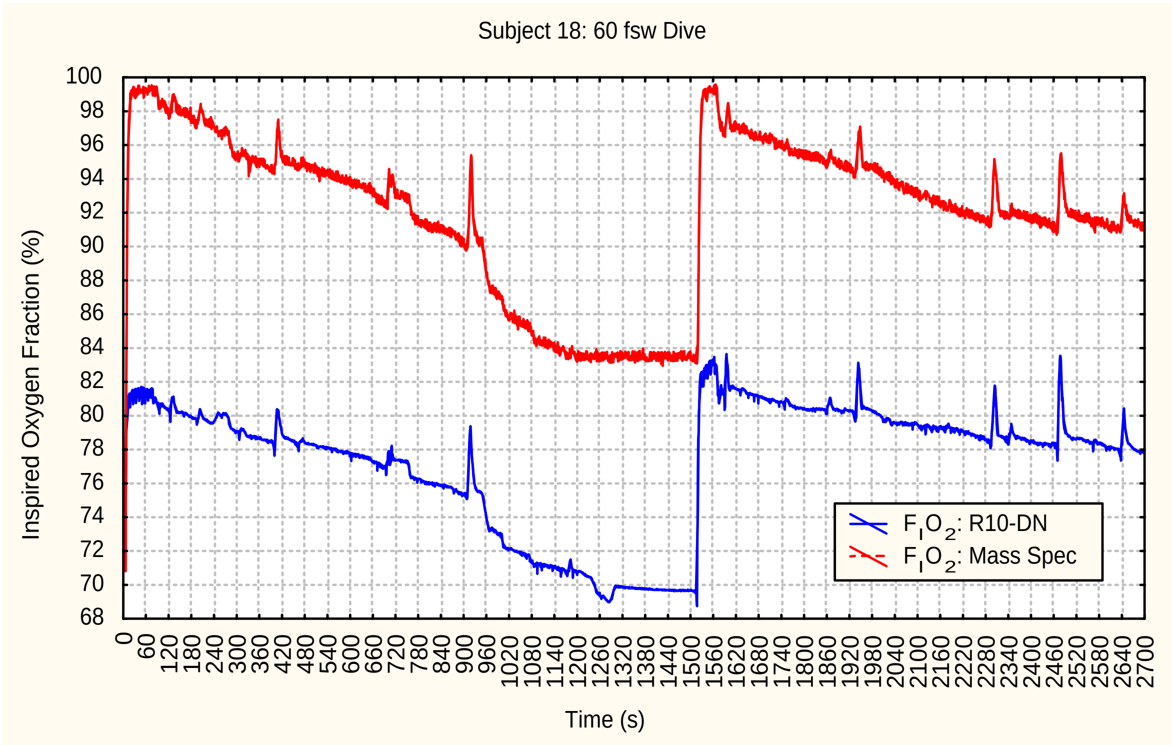
Subject 15: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec
O_2 Volume

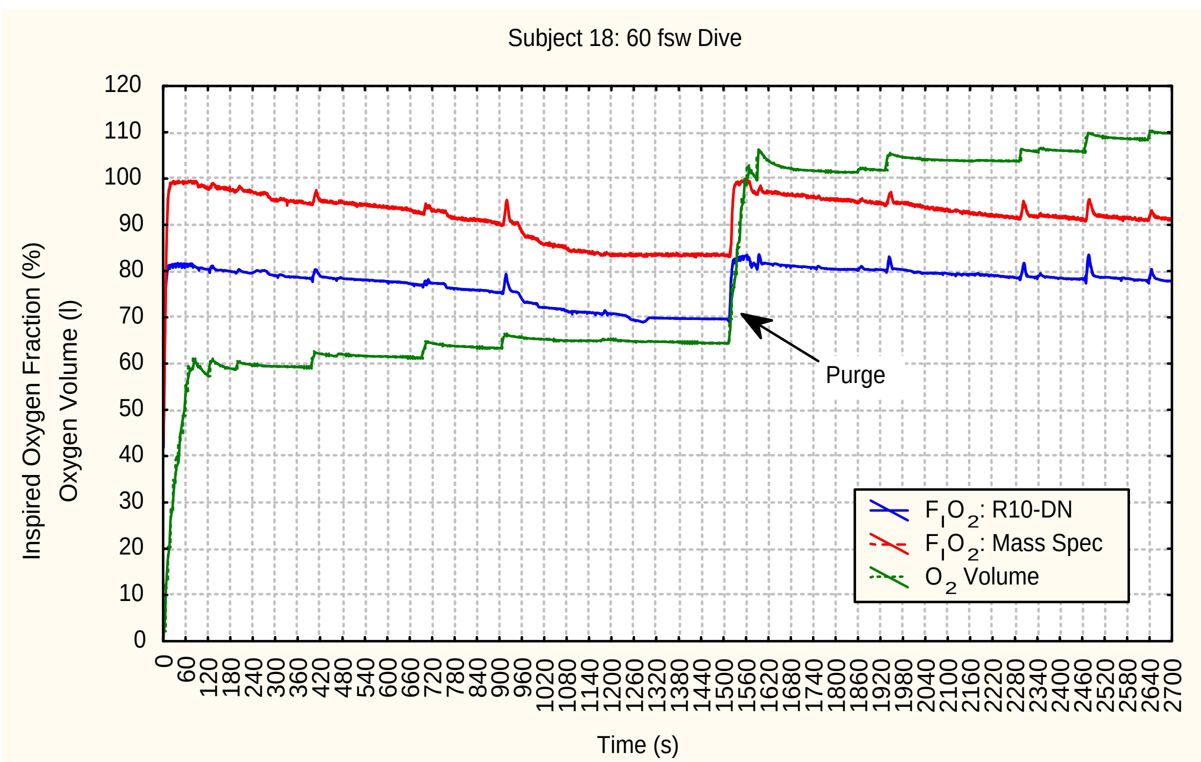

Subject 16: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass Spec


Subject 16: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec
O_2 Volume (l)


Subject 17: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
F_IO_2: R10-DN
F_IO_2: O_2 Analyser


Subject 17: 60 fsw Dive
Regulator for oxygen bottle developed a small leak
Purge
Mask leaks around top of nose due
to T-bit forcing mask off face
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
F_IO_2: R10-DN
F_IO_2: O_2 Analyser
O_2 Volume


Subject 18: 60 fsw Dive
Inspired Oxygen Fraction (%)
Time (s)
F_IO_2: R10-DN
F_IO_2: Mass Spec


Subject 18: 60 fsw Dive
Inspired Oxygen Fraction (%)
Oxygen Volume (l)
Time (s)
Purge
F_IO_2: R10-DN
F_IO_2: Mass Spec
O_2 Volume